Originally Filed: May 14, 2018
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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| GENENTECH, INC., CITY OF HOPE, and HOFFMANN-LA ROCHE INC., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. 18-095-GMS |
| CELLTRION, INC., CELLTRION HEALTHCARE CO., LTD., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS INTERNATIONAL GMBH, | ) | REDACTED - PUBLIC VERSION |
| Defendants. | ) | |

**DECLARATION OF ANDREW J. DANFORD**

I, Andrew J. Danford, declare as follows:

1. I am a partner of the law firm Wilmer Cutler Pickering Hale and Dorr LLP, counsel for Genentech, Inc., City of Hope, and Hoffmann-La Roche Inc. (collectively, "Plaintiffs") in the above-captioned action. I am a member in good standing of the Bars of the Commonwealth of Massachusetts and State of New York, and I have applied to appear before this Court *pro hac vice* in this matter. I respectfully submit this declaration in support of Plaintiffs' Answering Brief in Opposition to Defendants' Motion to Dismiss or Stay.

2. Attached hereto as **Exhibit 1** is a true and correct copy of the Order Granting Defendants' Motion to Dismiss, ECF No. 81, in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274 (N.D. Cal.), dated May 9, 2018, retrieved by members of my firm from CM/ECF.

3. Attached hereto as **Exhibit 2** is a true and correct copy of a letter from E. Whelan to R. Cerwinski, re: CT-P6, aBLA No. 761091, dated October 10, 2017, containing Genentech's list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

4. Attached hereto as **Exhibit 3** is a true and correct copy of a letter from R. Cerwinski to R. Gunther, re: Celltrion's 42 U.S.C. § 262(*l*)(3)(B) List and Description for Biosimilar aBLA for Reference Product Herceptin®, dated November 7, 2017, excluding exhibits.

5. Attached hereto as **Exhibit 4** is a true and correct copy of a letter from E. Whelan to R. Cerwinski, re: CT-P6, aBLA No. 761091, dated January 5, 2018, including the attachment but excluding exhibits.

6. Attached hereto as **Exhibit 5** is a true and correct copy of an email from K. DeJong to R. Gunther, copying R. Cerwinski and E. Whelan, re: CT-P6, aBLA No. 761091, dated [redacted] and an attached letter from R. Cerwinski to R. Gunther, dated [redacted].

7. Attached hereto as **Exhibit 6** is a true and correct copy of the Notice of Electronic Filing for the Complaint, ECF No. 1, in *Celltrion, Inc. v. Genentech, Inc.*, No. 3:18-cv-00274 (N.D. Cal.), dated January 11, 2018, and bearing a timestamp of 6:20 P.M. PST, retrieved by members of my firm from CM/ECF.

8. Attached hereto as **Exhibit 7** is a true and correct copy of *2017 Patent Litigation Study: Change on the Horizon?*, PwC (May 2017), *available at* https://www.pwc.com/us/en/forensic-services/publications/assets/2017-patent-litigation-study.pdf, retrieved electronically on May 9, 2018.

I declare under penalty of perjury that the foregoing is true and correct. Executed on May 14, 2018, at Boston, Massachusetts.

Andrew J. Danford

**CERTIFICATE OF SERVICE**

I hereby certify that on May 21, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on May 21, 2018, upon the following at the email addresses indicated below:

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# EXHIBIT 1

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

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|---|---|
| CELLTRION, INC., et al.,<br>Plaintiffs,<br>v.<br>GENENTECH, INC., et al.,<br>Defendants. | Case No. 18-cv-00274-JSW<br><br>Re: Dkt. No. 53 |

| | |
|---|---|
| CELLTRION, INC., et al.,<br>Plaintiffs,<br>v.<br>GENENTECH, INC., et al.,<br>Defendants. | Case No. 18-cv-00276-JSW<br><br>**ORDER GRANTING DEFENDANTS' MOTIONS TO DISMISS**<br><br>Re: Dkt. No. 47 |

Now pending before the Court are two motions to dismiss filed by Defendants Genentech, Inc., Hoffman La-Roche, Inc., and City of Hope ("Defendants" or "Genentech") to dismiss the first amended complaint filed by Plaintiffs Celltrion, Inc., Celltrion Healthcare, Co. Ltd., Teva Pharmaceuticals International GMGH, and Teva Pharmaceuticals USA, Inc. ("Plaintiffs" or "Celltrion"). The Court has considered the parties' papers, relevant legal authority, and the record in this case, and the Court finds both motions suitable for disposition without oral argument. *See* N.D. Civ. L.R. 7-1(b). For the reasons set forth below, the Court HEREBY GRANTS Defendants' motions to dismiss, but will afford Plaintiffs leave to amend.

## BACKGROUND

### A. "Biologic" and "Biosimilar" Drugs.

These cases concern a portion of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). 42 U.S.C. § 262(*l*). The BPCIA concerns, in part, approval of "biologic" and "biosimilar" drugs by the Food and Drug Administration ("FDA").

"Biologic" drugs (drugs derived from natural biological sources rather than chemically synthesized) may only be sold to consumers following approval and licensure by the FDA. *Sandoz Inc. v. Amgen Inc.*, ___ U.S. ___, 137 S. Ct. 1664, 1669-70 (2017). A biologic licensed by the FDA is known as a "reference product," and the party who manufactures the reference product is known as the "sponsor" or "reference product sponsor." *Id*. at 1670. "Biosimilar" drugs, in essence, are products "highly similar" to biologic products the FDA has already approved. *Id.* at 1669. Under the BPCIA, a party who wishes to manufacture a biosimilar drug may apply to the FDA and, upon a showing that there are no "clinically meaningful differences" between the biosimilar drug and the biologic drug, may "piggyback" off of the biologic drug's license and procure FDA approval for the biosimilar drug. *Id.* at 1670. Applying to the FDA in order to "piggyback" is technically patent infringement. *See* 35 U.S.C. § 271(e)(2)(C).

### B. BPCIA Process for Biosimilar Drugs.

Reference products may be covered by multiple patents, and 42 U.S.C. § 262(*l*) ("Section (*l*)") prescribes a detailed mechanism for resolving infringement claims arising between the reference party sponsor and the biosimilar applicant. *Sandoz*, 137 S. Ct. at 1670. Colloquially, attorneys practicing in this space refer to these steps as the "patent dance."

First, within twenty days of receiving notice that the FDA has accepted its biosimilar application for review, the applicant (here, Celltrion) must send to the reference product sponsor (here, Genentech) (i) the biosimilar application and (ii) information about the processes for manufacturing the biosimilar product (collectively, the "2(A) Disclosure"). 42 U.S.C. § 262(*l*)(2)(A). Sixty days after the reference product sponsor receives the 2(A) Disclosure, it must provide the applicant with a "list of patents" the reference product sponsor believes the biosimilar drug infringes (the "3(A) Disclosure"). *Id.* § 262(*l*)(3)(A)(i). The

reference product sponsor must also identify which patents in the 3(A) Disclosure it would be willing to license to the applicant. *Id.* § 262(*l*)(3)(A)(ii).

Within sixty days of receiving the 3(A) Disclosure, the applicant must send the reference product sponsor its (i) claim-by-claim arguments for noninfringement, invalidity, and/or unenforceability of the patents identified in the 3(A) Disclosure; (ii) a response regarding the reference product sponsor's willingness to license certain patents; and, if applicable (iii) a statement that the applicant does not intend to begin commercial marketing of the biosimilar before certain patents expire (collectively, the "3(B) Disclosure"). *Id.* § 262(*l*)(3)(B). The applicant may also augment the reference product sponsor's 3(A) Disclosure by identifying additional patents the reference product sponsor could assert against the biosimilar drug. *Id.* § 262(*l*)(3)(B)(i). Within sixty days of receiving the 3(B) Disclosure from the applicant, the reference product sponsor must respond, claim-by-claim, to the applicant's noninfringement, invalidity, and unenforceability arguments ("3(C) Disclosure"). *Id.* § 262(*l*)(3)(C).

Following the exchange of the 3(A), (B), and (C) Disclosures, the applicant and the reference product sponsor must engage in "good faith negotiations" to reach an agreement identifying which patents will be the subject of "immediate" patent infringement litigation. *Id.*§ 262(*l*)(4)(A), (*l*)(6). The negotiations kick off the so-called "Phase I" patent litigation. *Sandoz*, 137 S. Ct. at 1671. Once these negotiations begin, the reference product sponsor and the applicant have fifteen days to reach agreement. 42 U.S.C. § 262(*l*)(4)(B). If they cannot agree on a list of patents for Phase I "within" that window, the parties must simultaneously exchange lists of patents each believes should be immediately litigated (the "5(B) Lists"). *Id.* § 262(*l*)(4)(B), (*l*)(5)(B)(i), (*l*)(6). However, before the parties exchange 5(B) Lists, the applicant must identify the *number* of patents it will identify on its own 5(B) List (the "5(A) Number"). *Id.* § 262(*l*)(5)(A). The applicant's proffered number caps the number of patents the reference product sponsor may include on its 5(B) List.[1] *Id.* § 262(*l*)(5)(B)(ii). The reference product

[1] In the event the applicant indicates it will identify no patents, the reference product sponsor may always include at least one patent on its 5(B) List.

sponsor then has thirty days after the exchange of the 5(B) Lists to bring patent infringement claims regarding all patents on those lists. *Id.* § 262(*l*)(6)(B).[2]

"Phase II" litigation, meant to address patents included on the 3(A)-(C) Disclosures but "not litigated" in "Phase I," begins when the applicant serves the reference product sponsor a "notice of commercial marketing," which it must do at least 180 days before marketing the biosimilar. *Id.* § 262(*l*)(8)(A); *Sandoz*, 137 S. Ct. at 1671-72.

The parties' available remedies are contingent upon their compliance with these steps. If an applicant fails to provide its 2(A) Disclosure, it may not bring an action for declaratory judgment for noninfringement, validity, or enforceability of any patent covering the biologic drug. 42 U.S.C. § 262(*l*)(9)(C). If an applicant provides its 2(A) Disclosure, then neither party may bring a declaratory judgment action regarding infringement, validity, or enforceability of a subset of the patents at issue[3] before the applicant serves its notice of commercial marketing (the initiation of Phase II litigation). *Id.* § 262(*l*)(9)(A). Finally, if an applicant: (i) fails to serve its 3(B) Disclosure[4], 5(A) Number, 5(B) List, or notice of commercial marketing; (ii) timely notify the FDA of an ensuing patent lawsuit; or (iii) supplement its 3(B) Disclosure in response to newly issued or licensed patents the reference product sponsor identifies, the applicant may not bring an action for declaratory judgment. *Id.* § 262(*l*)(9)(B).

**C. Genentech and Celltrion's BPCIA "Patent Dance."**

**1. "Herceptin" and "Herzuma."**

Genentech is the reference product sponsor for a biologic called "Herceptin." *See* First Amended Complaint, No. 18-cv-000274-JSW ("Herceptin FAC") ¶ 36. On May 30, 2017,

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[2] The reference product sponsor must file for patent infringement for any patent appearing on either its or the applicant's 5(B) Lists.

[3] This subset includes patents on the 3(A) *or* (B) Disclosures, but not encompassed by (i) any agreement the parties reach regarding patents suitable for "immediate" litigation *or* (ii) itemized on the 5(B) Lists.

[4] The only components of the 3(B) Disclosure necessary to avoid Section (l)(9)(B)'s prohibition are (i) the applicant's arguments on invalidity, unenforceability, and/or noninfringement and (ii) any statement by the applicant that it does not intend to begin commercial marketing of the biosimilar before the expiration of certain patents.

pursuant to 42 U.S.C. § 262(k), Celltrion applied for FDA approval to market a biosimilar of Herceptin called "Herzuma." *Id.* ¶¶ 5, 37. The FDA notified Celltrion on July 28, 2017 that its application had been accepted for review. *Id.* On August 11, 2017, well within the statutory deadline, Celltrion sent its 2(A) Disclosure to Genentech.[5] *Id.* ¶¶ 5, 15, 39; 42 U.S.C. § 262(*l*)(2)(A).

On October 10, 2017, Genentech provided Celltrion with its 3(A) Disclosure, listing 40 patents it believed Herzuma would infringe, and, on November 7, 2017, Celltrion responded with its 3(B) Disclosure. Herceptin FAC ¶¶ 5, 15, 41, 42; 42 U.S.C. § 262(*l*)(3)(A), (B). On January 5, 2018, Genentech timely sent its 3(C) Disclosure to Celltrion. Herceptin FAC ¶¶ 5, 15, 46; 42 U.S.C. § 262(*l*)(3(C). Simultaneously, Genentech, evidently intending to begin the statutorily mandated "good faith negotiations," proposed the parties agree to litigate a discrete number (fewer than all)[6] of the patents under discussion. Herceptin FAC ¶ 48; 42 U.S.C. § 262(*l*)(4)(A). Celltrion responded by stating that it wished to litigate a larger number of patents than Genentech's opening offer: namely, *all* patents listed on the 3(A) Disclosure. Herceptin FAC ¶ 49; 42 U.S.C. § 262(*l*)(4)(A).

Celltrion then served a notice of commercial marketing on Genentech. Herceptin FAC ¶¶ 6, 16, 49; 42 U.S.C. § 262(*l*)(8)(A). Celltrion did not provide Genentech with the 5(A) Number or engage in simultaneous exchange of 5(B) Lists with Genentech. *See generally* Herceptin FAC; 42 U.S.C. § 262(*l*)(5). Celltrion filed a declaratory judgment lawsuit regarding these patents (the "Herceptin Lawsuit" or "Herceptin Complaint") on January 11, 2018. Dkt. 1.

**2. "Rituxan" and "Truxima."**

Genentech is also the reference product sponsor for a biologic called "Rituxan." *See* First

[5] The Court is aware that Genentech contests the sufficiency of Celltrion's 2(A) Disclosures for both biosimilars. Celltrion alleges, in each complaint, it served complete 2(A) Disclosures. As explained below, the Court's analysis is properly limited to the allegations in the complaint. The Court therefore declines to address the sufficiency of Celltrion's 2(A) Disclosures at this time.

[6] The specific information regarding Genentech's proposal is the subject of a motion to seal.

Amended Complaint, No. 18-cv-000276-JSW ("Rituxan FAC") ¶ 41. On April 28, 2017, pursuant to 42 U.S.C. § 262(k), Celltrion applied for FDA approval to market a biosimilar of Rituxan called "Truxima." *Id.* ¶¶ 6, 42. The FDA notified Celltrion on June 27, 2017 that its application had been accepted for review. *Id.* On July 17, 2017, Celltrion sent its 2(A) Disclosure regarding Truxima to Genentech. *Id.* ¶¶ 6, 44; 42 U.S.C. § 262(*l*)(2)(A).

On September 14, 2017, Genentech provided Celltrion with its 3(A) Disclosure for Rituxan, listing 40 patents it believed Celltrion's biosimilar would infringe, and, on November 7, 2017, Celltrion responded in kind with its 3(B) Disclosure. Rituxan FAC ¶¶ 5, 46, 47; 42 U.S.C. § 262(*l*)(3)(A), (B). On January 5, 2018, Genentech timely sent its 3(C) Disclosure to Celltrion. Rituxan FAC ¶¶ 6, 51; 42 U.S.C. § 262(*l*)(3(C). On January 11, 2018, evidently as part of Section (*l*)4's "good faith negotiations," Celltrion indicated it wished to litigate all forty patents on Genentech's 3(A) Disclosure. Rituxan FAC ¶ 53; 42 U.S.C. § 262(*l*)(4)(A). Celltrion then served a notice of commercial marketing on Genentech. Rituxan FAC ¶¶ 7, 54; 42 U.S.C. § 262(*l*)(8)(A). Celltrion did not provide Genentech with the 5(A) Number or engage in simultaneous exchange of 5(B) Lists with Genentech. *See generally* Rituxan FAC; 42 U.S.C. § 262(*l*)(5). Celltrion filed a declaratory judgment lawsuit regarding these patents (the "Rituxan Lawsuit" or "Rituxan Complaint") on January 11, 2018. Dkt.1.

## ANALYSIS

### A. Applicable Legal Standard.

In its motions to dismiss, Genentech seeks to dismiss both the Herceptin and Rituxan Lawsuits for lack of subject matter jurisdiction or, in the alternative, for failure to state a claim. The Court finds that Genentech's motions are both properly construed as motions to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6).

Federal courts have subject matter jurisdiction over "all civil actions arising under the Constitution, laws, or treatises of the United States." 28 U.S.C. § 1331. Additionally, a specific statutory grant of jurisdiction gives federal district courts subject matter jurisdiction over "any civil action arising under any Act of Congress relating to patents." *Id.* § 1338(a). This Court therefore incontrovertibly has subject matter jurisdiction over the patent disputes in both the

Herceptin and Rituxan Lawsuits.

Despite this mandate, Genentech contends that Celltrion's failure to perform the BPCIA's "patent dance" deprives this Court of jurisdiction. The Supreme Court, however, has repeatedly admonished courts to avoid "drive-by jurisdictional rulings" which fail to properly distinguish between a lack of subject matter jurisdiction and a plaintiff's failure to state a claim. *See Arbaugh v. Y&H Corp.*, 546 U.S. 500, 511 (2006). To discourage inappropriate challenges to subject matter jurisdiction, the Supreme Court developed the "clear statement" rule: courts should treat statutory requirements as nonjurisdictional unless there is a clear legislative statement to the contrary. *Id.* at 515-16.[7] Here, Genentech has cited no "clear statement" by Congress suggesting that Congress intended the BPCIA's requirements to be jurisdictional prerequisites. Rather, a review of the BPCIA reveals that the "patent dance" is a series of statutory conditions an applicant must satisfy before bringing an action for declaratory judgment. *See Castillo v. U.S. I.R.S.*, No. 13-cv-00517-AWI, 2014 WL 1270548, at *4 (E.D. Cal. Mar. 26, 2014) ("Such claim processing rules are not jurisdictional unless Congress specifically attached jurisdictional consequences to such rules."); *cf. Yagman v. Pompeo*, 868 F.3d 1075 (9th Cir. 2017) (finding Freedom of Information Act's exhaustion requirements not "jurisdictional" in nature).

Accordingly, the Court treats Genentech's motions as seeking dismissal for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). Under this standard, courts construe complaints in the light most favorable to the non-moving party. *Sanders v. Kennedy*, 794 F.2d 478, 481 (9th Cir. 1986).[8] The plaintiff need only provide a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). This requires the

[7] In subsequent opinions, the Supreme Court has telegraphed a consistently conservative approach to classifying rules as jurisdictional. *See, e.g.*, *Sebelius v. Auburn Regional Medical Center, et al.*, 568 U.S. 145, 153 (2013) ("Tardy jurisdiction objections can therefore result in a waste of adjudicatory resources and can disturbingly disarm litigants.")

[8] Even if Genentech's arguments did constitute proper challenges to subject matter jurisdiction, this Court's analysis would not change. The disagreement between the parties is not whether key actions giving rise to this Court's jurisdiction occurred, but the meaning and effect of actions alleged in the complaints: facial, not factual, challenges. *See Wolfe v. Strankman*, 392 F.3d 358, 362 (9th Cir. 2004) (observing defendant's argument concerned adequacy, not accuracy, of allegations).

plaintiff to provide "more than labels and conclusions:" mere "recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). The Court may consider the facts alleged in the complaint, documents attached to the complaint, documents relied upon but not attached to the complaint (when the authenticity of such documents is not questioned), and other matters of which the Court can take judicial notice. *Zucco Partners LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009). Unless amendment would be futile, the Court should freely grant leave to amend. *Reddy v. Litton Indus., Inc.*, 912 F.2d 291, 296 (9th Cir. 1990).

**C. Celltrion's Declaratory Judgment Actions Fail Under Section (*l*)(9)(B) of the BPCIA.**

Examining the complaints, and drawing all reasonable inferences in Celltrion's favor, Celltrion fails to state a claim for relief in either the Herceptin or Rituxan Complaint. Because Celltrion did not complete its obligations under Section (*l*)(5), Celltrion may not file actions for declaratory judgment with respect to the patents at issue.

**1. Celltrion Did Not Complete the Statutorily Required Patent Dance.**

In the Herceptin and Rituxan Complaints, Celltrion alleges that the parties completed their respective Section 2(A), 3(A), 3(B), and 3(C) Disclosure obligations. *See* Herceptin FAC ¶¶ 39, 41, 42, 46; Rituxan FAC ¶¶ 44, 46, 47, 51. In the Herceptin FAC, Celltrion then alleges that the parties began Section (*l*)(4)'s "good faith negotiation" process, but were unable to agree on which patents were suitable for "immediate" Phase I litigation. *See* Herceptin FAC ¶¶ 48, 49. At this juncture, the express terms of the BPCIA required both Celltrion and Genentech to complete the steps outlined in Section (*l*)(5). *See* 42 U.S.C. § 262(*l*)4, (*l*)(5). Yet, Celltrion never alleges that it either (i) sent its 5(A) Number to Genentech, or (ii) that the parties simultaneously exchanged 5(B) lists.

The Rituxan FAC is similarly deficient. Celltrion's allegations reveal that Celltrion began the Section (*l*)(4) negotiation process by indicating that it wanted to litigate all the patents contained on Genentech's 3(A) Disclosure, but then did not wait for Genentech to respond. *See* Rituxan FAC ¶¶ 53, 54. There are no allegations that Celltrion sent its 5(A) Number or exchanged 5(B) Lists with Genentech. Instead, Celltrion contends that it served Genentech with a notice of

commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) and then filed suit. *Id.* ¶ 54.

Section (*l*)(9)(B) provides: "If [an applicant] fails to complete an action required . . . under . . . paragraph (5) . . . the reference product sponsor, *but not the* [*applicant*], may bring an action . . . for a declaration of infringement, validity, or enforceability of any patent included in the list described in [the Section 3(A) Disclosure]." 42 U.S.C. § 262(*l*)(9)(B) (emphasis added). Thus, "when an applicant . . . fails to complete a subsequent step [in the patent dance] . . . the [reference product] sponsor, but not the applicant, may bring a declaratory-judgment action with respect to any patent included on the sponsor's [list of relevant patents]." *Sandoz*, 137 S. Ct. at 1672; *see also Celltrion Healthcare Co., Ltd. v. Kennedy Trust for Rheumatology Research*, 14-cv-2256-PAC, 2014 WL 6765996, at *2 (S.D.N.Y. Dec. 1, 2014) ("Neither party may bring a declaratory judgment action while the process is under way; if the applicant fails to comply with these procedures, the reference product sponsor may bring a declaratory judgment action, but the applicant may not."). Celltrion fails to allege, in either complaint, that it provided Genentech with its 5(A) Number or simultaneously exchanged 5(B) lists with Genentech. In these circumstances, the BPCIA is clear: Celltrion may not bring a declaratory judgment action with respect to any patent on Genentech's Section 3(A) Disclosures.

**2. Celltrion's Arguments Conflict with the Plain Meaning of the BPCIA.**

Celltrion's arguments as to why its failures to comply with the BPCIA's requirements do not bar this suit are unavailing.

First, Celltrion suggests it may streamline its obligations under the statute and satisfy several steps at once. In support of the Herceptin Complaint, Celltrion argues that it is absolved of the responsibility to comply with Section (*l*)(5) because it told Genentech it "wished" to litigate all patents on Genentech's 3(A) Disclosure. Celltrion contends that this statement both fulfilled its obligations to engage in "good faith negotiations" under Section (*l*)(4) and made the exchange of the 5(A) Number and 5(B) Lists "redundant."

This argument, however, improperly conflates Sections (*l*)(4) and (*l*)(5). The parties' obligations under Section (*l*)(5) only arise if the parties are unable to agree, after fifteen days of good faith negotiations, on a final and complete list of patents to litigate in Phase I. *See* 42 U.S.C.

§ 262 (*l*)(4)(B). Given the plain language of this provision, and the relationship between Sections (*l*)(4) and (*l*)(5) more generally, the Court concludes that no single statement or gesture can satisfy the requirements of both sections simultaneously. Celltrion's assertion that it "wished" to litigate all the patents on Genentech's 3(A) Disclosure was merely a response to Genentech's initial proposition and therefore part of the Section (*l*)(4) negotiation process.

In defense of the Rituxan Complaint, Celltrion argues that it completed its obligations under Section (*l*)(4) by indicating it wished to litigate all listed patents because Genentech had, in its 3(A) Disclosure, "reserved its rights" to litigate all patents. Thus, according to Celltrion, there was nothing left to negotiate. In so arguing, Celltrion suggests that the 3(A), (B), and (C) Disclosures are somehow part of the Section (*l*)(4) negotiations, when they are, in fact, distinct statutory steps which the parties must complete before commencing the Section (*l*)(4) negotiations. 42 U.S.C. § 262(*l*)(4) ("*After* receipt by the [applicant] of the [3(C) Disclosure], the reference product sponsor and the [applicant] shall engage in good faith negotiations to agree on which, if any, patents listed [in the 3(A), (B), and (C) Disclosures] shall be the subject of an action for patent infringement under paragraph (6)." (emphasis added)). The statutory procedures do not allow an applicant to collapse its multiple distinct obligations into one or two perfunctory actions.

Moreover, Celltrion's arguments in support of both complaints presuppose that, once the Section (*l*)(4) good faith negotiations began, any disagreement (or presumed disagreement) as to the desired scope of Phase I patent litigation permitted Celltrion to unilaterally terminate negotiations and end the patent dance. Yet, Celltrion provides no authority for the proposition that Section (*l*)(4) or (*l*)(5) requirements are excused if one party believes continued negotiation is futile. Further, Celltrion's position runs counter to the principles and realities of negotiation. Negotiation would be entirely unnecessary if the initial positions of the reference party sponsor and the applicant were identical: the aim of negotiation, not the starting point, is agreement.

Even assuming, *arguendo*, that Celltrion's characterizations of its obligations under Section (*l*)(4) were correct, Celltrion failed to follow any statutorily prescribed path. If, after

completing Section (*l*)(4)'s "good faith negotiations," the parties had agreed[9] upon the patents they wanted to litigate in Phase I, the statute directed the reference product sponsor Genentech—not applicant Celltrion—to file a patent infringement lawsuit. 42 U.S.C. § 262(*l*)(6)(A). On the other hand, if, at the end of "good faith negotiations" the parties had not agreed on the scope of Phase I patent litigation, Celltrion was obligated to offer its 5(A) Number and then exchange 5(B) Lists. Even under this circumstance, the BPCIA commands Genentech—not Celltrion—to file a patent infringement action. *Id.* § 262(*l*)(6)(B). Neither path permitted Celltrion to file these declaratory judgment actions.

Second, Celltrion argues that it is not obligated to offer its 5(A) Number or exchange 5(B) Lists because it filed this lawsuit nine days before the expiration of the fifteen-day period Section (*l*)(4) allots for good faith negotiation. By this argument, Celltrion suggests that the filing of this declaratory judgment action was permissible *because* it skipped required statutory steps, where the non-occurrence of those statutory steps explicitly bars Celltrion from filing this action—an unpersuasive legal Catch-22[10]. Celltrion was obligated to complete all required procedures before filing this lawsuit, and it did not.

Finally, Celltrion argues that the notices of commercial marketing it served for Herzuma and Truxima enable it to file these declaratory judgment actions, regardless of its compliance with other portions of the BPCIA. The Court disagrees.

Section (*l*)(9) contains three separate, independent statutory bars, each of which applies to

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[9] Of course, it is not at all clear from the Rituxan Complaint that the parties were "in agreement" in wanting to litigate all patents on Genentech's 3(A) Disclosure. In fact, the complaint suggests the exact opposite. Genentech's 3(C) Disclosure demonstrates it was then focusing its attention upon a considerably smaller number of patents than it had originally set forth in its 3(A) Disclosure. Rituxan FAC ¶¶ 46-53. Celltrion's position, after receiving the 3(C) Disclosure, was to press for litigation of all patents on the 3(A) Disclosure.

[10] "There was only one catch and that was Catch-22, which specified that a concern for one's safety in the face of dangers that were real and immediate was the process of a rational mind. Orr was crazy and could be grounded. All he had to do was ask; and as soon as he did, he would no longer be crazy and would have to fly more missions. Orr would be crazy to fly more missions and sane if he didn't, but if he was sane he had to fly them. If he flew them he was crazy and didn't have to; but if he didn't want to he was sane and had to." Joseph Heller, *Catch-22* 46 (Simon & Schuster 2004) (1961).

distinct factual circumstances where applicants fail to comply with certain steps. Section (*l*)(9)(C) applies when an applicant has not completed a 2(A) Disclosure. 42 U.S.C. § 262(*l*)(9)(C). Section (*l*)(9)(B) applies where an applicant has failed to complete any *one* of five specifically identified statutory steps (including Section (*l*)(5)). *Id.* § 262(*l*)(9)(B). And Section (*l*)(9)(A) imposes a temporary statutory bar that begins when a reference product sponsor receives an applicant's 2(A) Disclosure and ends when an applicant serves a notice of commercial marketing. *Id.* § 262(*l*)(9)(A).

Celltrion contends that because a notice of commercial marketing lifts the ban on declaratory judgment actions described in Section (*l*)(9)(A), a notice of commercial marketing should also lift Sections (*l*)(9)(B) and (C)'s prohibitions. By the explicit text of the statute, however, serving a notice of commercial marketing lifts the prohibition imposed by Section (*l*)(9)(A)—and Section (*l*)(9)(A) alone. *See Sandoz*, 137 S. Ct. at 1672 (reasoning Section (*l*)(9)(B) applies when "an applicant provides the application and manufacturing information but fails to complete a subsequent step"); *see also Amgen, Inc. v. Apotex, Inc.*, 827 F. 3d 1052, 1057 (Fed. Cir. 2016) (Section (*l*)(9)(B) addresses applicants "that begin but do not complete" the Section 262(*l*) processes).

The Central District of California considered and rejected a similar argument in *Amgen v. Genentech, Inc.*, 17-cv-7349-GHW, 2018 WL 910198 (C.D. Cal. Jan. 11, 2018). There, the applicant served a notice of commercial marketing and filed a declaratory judgment lawsuit before the parties had completed the 5(A) Number and 5(B) List exchanges. *Id.* at * 3-4. The court, discussing *Sandoz*, observed that to allow an applicant to bring suit after serving its notice of commercial marketing but before completing the rest of the BPCIA's Section (*l*)(5) exchanges would "override congressional intent and do away with the 'carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement' set out in the BPCIA." *Id.* (citing *Sandoz*, 137 S.Ct. at 1670); *see also Sandoz*, 137 S.Ct. at 1675 (BPCIA's "carefully crafted and detailed enforcement scheme" provides "strong evidence" Congress did not intend to imply extra-statutory loopholes) (citation omitted). In other words, a notice of commercial marketing only opens the door for an applicant to file a declaratory judgment action if the applicant complies

with the rest of the statute. A notice of commercial marketing is no *carte blanche*, and Celltrion points to no authority that offers a contradictory interpretation.

As Celltrion has failed to state a claim, the Court declines to address the issue of whether it would exercise its jurisdiction under the Declaratory Judgment Act.[11]

**CONCLUSION**

For the foregoing reasons, the Court GRANTS both motions to dismiss. The Court will, however, afford Plaintiffs leave to amend, to the extent that the identified deficiencies can be corrected consistent with counsels' obligations under Federal Rule of Civil Procedure 11. Should Celltrion choose to file an amended complaint, it shall do so by June 10, 2018.

IT IS SO ORDERED.

Dated: May 9, 2018

JEFFREY S. WHITE
United States District Judge

[11] In 18-cv-00274-JSW, Celltrion seeks to seal the first complaint, first amended complaint, and its opposition to Genentech's motion to dismiss. Dkts. 5, 39, 66. In turn, Genentech requests sealing of its motion to dismiss and reply brief in support. Dkts. 52, 70. In 18-cv-00276-JSW, Celltrion seeks to seal the first amended complaint and its opposition to Genentech's motion to dismiss. Dkts. 39, 62. Genentech requests sealing of its motion to dismiss and reply brief in support. Dkts. 49, 69. The Court grants all requests to seal.

# EXHIBIT 2

WILMERHALE

October 10, 2017

**Emily R. Whelan**

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emily.whelan@wilmerhale.com

***Via Electronic Mail***

Robert V. Cerwinski, Esq.
Goodwin Procter LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018-1405

**Re: CT-P6, aBLA No. 761091**

Dear Mr. Cerwinski:

I write concerning Celltrion's aBLA No. 761091. As we have previously explained, Genentech does not believe Celltrion has complied with its obligations under 42 U.S.C. § 262(*l*)(2), a condition precedent to Genentech's obligation to produce a list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). Genentech requested specific manufacturing information and identified specific deficiencies in Celltrion's production in letters dated August 1, 2017, and September 19, 2017, and explained why the missing information was necessary to evaluate whether Celltrion's proposed product infringes specific Genentech patents. Just yesterday—weeks after Genentech's requests—Celltrion refused to produce this information in contravention of the statute.

Celltrion's non-compliance will be resolved in due course. If a court agrees with Genentech that Celltrion has not complied with 42 U.S.C. § 262(*l*)(2), Genentech will pursue all remedies available, including an order that aBLA No. 761091 is improper and that the FDA may not review or approve it; an order requiring Celltrion to comply with 42 U.S.C. § 262(*l*)(2); an order declaring that Genentech's operative list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) is not due until that occurs; and any other appropriate relief.

Subject to and without waiver of any of the foregoing, should a court determine Celltrion complied with 42 U.S.C. § 262(*l*)(2), the following list constitutes Genentech's list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) that it believes reasonably could be asserted against Celltrion's proposed CT-P6 product based upon a review of the product's aBLA filing. Genentech is not prepared to license any of these patents to Celltrion.

Genentech reserves all rights to supplement or revise this list, including in light of additional information provided by Celltrion.

Best regards,

Emily R. Whelan

**Patents Disclosed Pursuant to 42 U.S.C. § 262(*l*)(3)(A)**

| | | |
|---|---|---|
| 6,121,428 | 7,449,184 | 8,574,869 |
| 6,242,177 | 7,485,704 | 8,633,302 |
| 6,331,415 | 7,501,122 | 8,691,232 |
| 6,339,142 | 7,807,799 | 8,771,988 |
| 6,407,213 | 7,846,441 | 8,822,655 |
| 6,417,335 | 7,892,549 | 9,047,438 |
| 6,489,447 | 7,923,221 | 9,080,183 |
| 6,586,206 | 7,993,834 | 9,249,218 |
| 6,610,516 | 8,076,066 | 9,428,548 |
| 6,620,918 | 8,357,301 | 9,428,766 |
| 6,627,196 | 8,425,908 | 9,487,809 |
| 6,716,602 | 8,440,402 | 9,714,293 |
| 7,371,379 | 8,460,895 | |
| 7,390,660 | 8,512,983 | |

# EXHIBIT 3
# FULLY REDACTED

# EXHIBIT 4

WILMERHALE

January 5, 2018

**Emily R. Whelan**

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emily.whelan@wilmerhale.com

***Via Electronic Mail***

Robert V. Cerwinski, Esq.
Goodwin Procter LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018-1405

**Re: CT-P6, BLA No. 761091**

Dear Mr. Cerwinski:

Enclosed is Genentech's statement in accordance with 42 U.S.C. § 262(*l*)(3)(C) ("3C Statement"). Genentech is providing its 3C Statement subject to the objections in my October 10, 2017 letter and the objections explained in the 3C Statement.

Under the Biologics Price Competition and Innovation Act ("BPCIA"), Genentech and Celltrion are now required to engage in good faith negotiations to select the patents that will be included in an action for patent infringement. *See* 42 U.S.C. § 262(*l*)(4)(A). We propose agreeing that all patents addressed in Genentech's 3C Statement be included in the infringement action under § 262(*l*)(6). Please let us know if that is agreeable to Celltrion. Otherwise, please let us know your availability next week to confer.

Genentech expressly reserves all rights to supplement or revise its 3C Statement and infringement and validity positions more generally, including in light of additional information provided by Celltrion.

Best regards,

Emily R. Whelan

REMAINDER OF EXHIBIT 4
REDACTED IN ITS ENTIRETY

# EXHIBIT 5

From: DeJong, Kevin J KDeJong@goodwinlaw.com
Subject: CT-P6, aBLA No. 761091
Date: [redacted]
To: Gunther, Jr., Robert J. Robert.Gunther@wilmerhale.com
Cc: Cerwinski, Robert V. RCerwinski@goodwinlaw.com, Whelan, Emily Emily.Whelan@wilmerhale.com

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Mr. Gunther,

Please see the attached correspondence regarding Celltrion's CT-P6 product, aBLA No. 761091.

Best regards,

Kevin

**Kevin J. DeJong**

GOODWIN

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Boston, MA 02210
o +1 617 570 1156
f +1 617 321 4714
KDeJong@goodwinlaw.com | goodwinlaw.com

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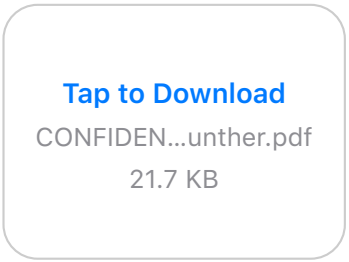
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# EXHIBIT 6

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Content-Type: text/html



**U.S. District Court**

**California Northern District**

## Notice of Electronic Filing

The following transaction was entered by Chatterjee, Indra on 1/11/2018 at 6:20 PM PST and filed on 1/11/2018

**Case Name:** Celltrion, Inc. et al v. Genentech, Inc. et al
**Case Number:** 3:18-cv-00274
**Filer:** Teva Pharmaceuticals International GmbH
Celltrion, Inc.
Teva Pharmaceuticals USA, Inc.
Celltrion Healthcare Co., Ltd.,
**Document Number:** 1

**Docket Text:**
**COMPLAINT *for Declaratory Judgment of Patent Non-Infringement, Invalidity, and/or Unenforceability* against City of Hope, Genentech, Inc., Hoffmann-La Roche Inc. ( Filing fee $ 400, receipt number 0971-12019225.). Filed byTeva Pharmaceuticals International GmbH, Celltrion, Inc., Teva Pharmaceuticals USA, Inc., Celltrion Healthcare Co., Ltd.,. (Attachments: # (1) Exhibit 1, # (2) Exhibit 2, # (3) Exhibit 3, # (4) Exhibit 4, # (5) Exhibit 5, # (6) Exhibit 6, # (7) Exhibit 7, # (8) Exhibit 8, # (9) Exhibit 9, # (10) Exhibit 10, # (11) Exhibit 11, # (12) Exhibit 12, # (13) Exhibit 13, # (14) Exhibit 14, # (15) Exhibit 15, # (16) Exhibit 16, # (17) Exhibit 17, # (18) Exhibit 18, # (19) Exhibit 19, # (20) Exhibit 20, # (21) Exhibit 21, # (22) Exhibit 22, # (23) Exhibit 23, # (24) Exhibit 24, # (25) Exhibit 25, # (26) Exhibit 26, # (27) Exhibit 27, # (28) Exhibit 28, # (29) Exhibit 29, # (30) Exhibit 30, # (31) Exhibit 31, # (32) Exhibit 32, # (33) Exhibit 33, # (34) Exhibit 34, # (35) Exhibit 35, # (36) Exhibit 36, # (37) Exhibit 37, # (38) Exhibit 38, # (39) Civil Cover Sheet)(Chatterjee, Indra) (Filed on 1/11/2018)**

**3:18-cv-00274 Notice has been electronically mailed to:**

Indra Neel Chatterjee NChatterjee@goodwinlaw.com, CLogan@goodwinlaw.com, JMcKenzie@goodwinlaw.com

**3:18-cv-00274 Please see Local Rule 5-5; Notice has NOT been electronically mailed to:**

The following document(s) are associated with this transaction:

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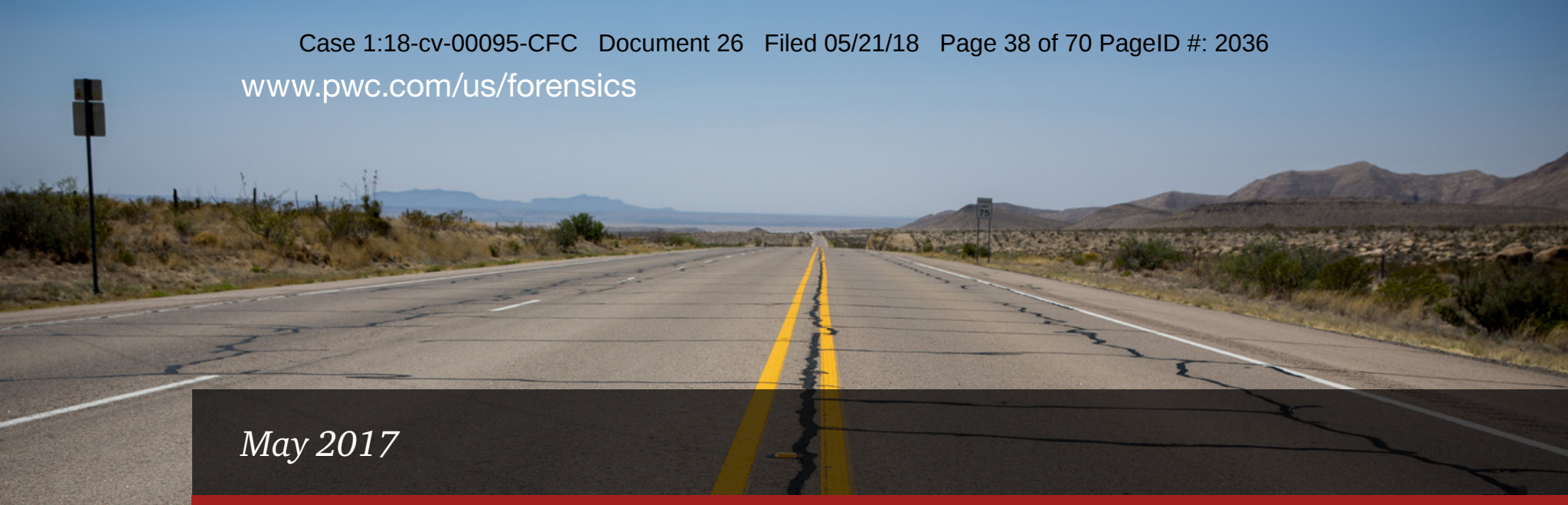
# EXHIBIT 7

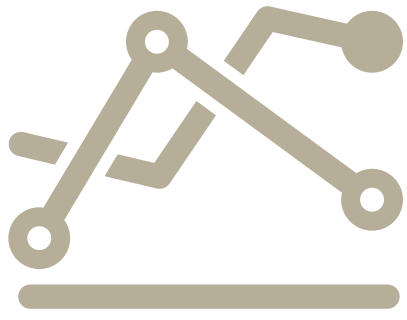
www.pwc.com/us/forensics



*May 2017*

# *2017 Patent Litigation Study*
# Change on the horizon?

**Despite Idenix mega-award, *median damages down 40%* relative to last year**



## Trends

- ***$2.5B*** Largest patent infringement award in US history granted to Idenix (Merck)
- ***9%*** fewer patent cases filed in 2016 v. 2015
- ***33%*** Patentee success rate steady
- ***80/20*** Jury versus bench proportion continues to rise (up from 75/25)
- ***15x*** Median jury award over 15x greater than median bench award in last 5 years
- ***52%*** of appealed decisions were modified in some regard

pwc

## SCOTUS: Significant developments

- **A shift in pleading standards.** The Supreme Court abolished Rule 84—effectively making it harder for smaller entities to bring patent suits
- ***Halo v. Pulse*** and ***Stryker v. Zimmer*** decisions address the tests for willfulness, easing the way to obtain punitive damages *(p. 10)*
- ***Apple v. Samsung*** levels the playing field between design patents and other types of patents, by imposing apportionment concept to design patent damages *(p. 12)*
- ***TC Heartland v. Kraft Foods*** could significantly restrict venue choice and further reduce patent litigation *(p. 23)*

## Industries and districts

- **Medical devices industry edges biotech/pharma industry in top median damages** while consumer products still leads in number of cases
- **Distribution of cases** continues to be skewed: filings grow in tech-rich California Northern and corporate-rich Delaware

## Nonpracticing entities (NPEs) vs. practicing entities (PEs)

- **NPE/Practicing Entities = 3.8x** Damages awards for NPEs in the last five years continue to widen relative to practicing entities (last year was 2.7x)
- Still, NPEs face **lower success rates** at trial and in summary judgments
- **NPE cases concentrated:** five of 94 district courts account for nearly half (46%) of all identified NPE decisions—Texas Eastern is favorite district for NPEs


# Table of contents

# *Overview:*
# What are the trends to watch?

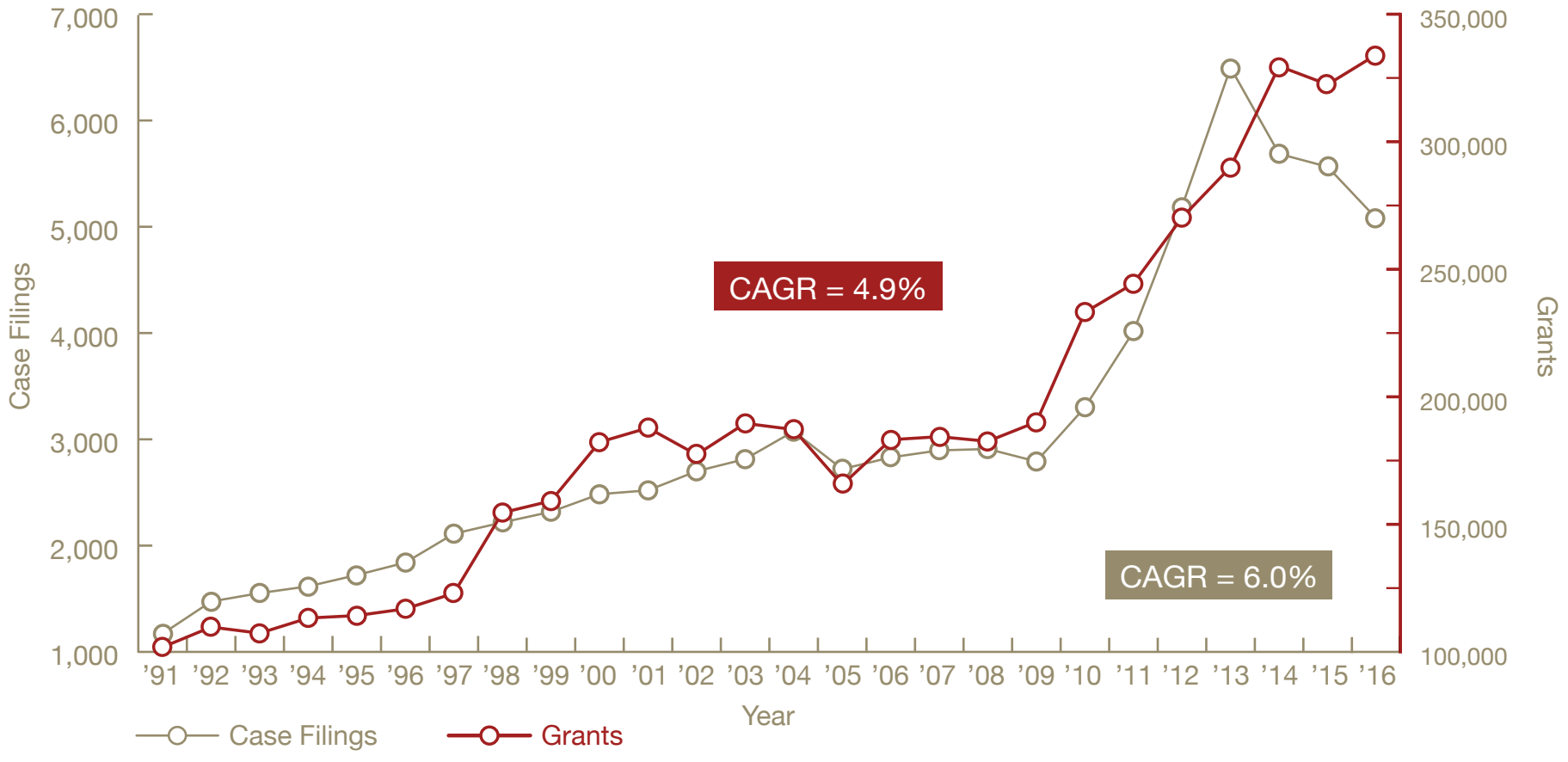
## Patent litigation continues sharp downturn, while grants bounce back

The number of patent cases filed declined again in 2016, continuing a downward trend from the high point reached in 2013. Approximately 5,100 cases were filed in 2016, representing a year-over-year drop of 9%—and growing evidence of a clear shift in direction.

What's behind the decline? One likely factor is an important change in pleading standards that took place in December 2015—namely, the abolishment of Rule 84 of the Federal Rules of Civil Procedure and its use of Form 18, which simplified the process of bringing a suit for direct patent infringement (especially useful for smaller companies and solo inventors). With this change, the default pleading standard for patents will be the heightened plausibility standards as set forth in *Bell Atlantic Corp. v. Twombly* and *Ashcroft v. Iqbal.*

The decline in the number of cases over the last three years stands in contrast to its compound annual growth rate (CAGR) since 1991, which has remained at 6%. At the same time, the number of patents granted by the US Patent and Trademark Office (USPTO) increased by 4% in 2016, after seeing a rare decline last year.

**Fig 1: Patent case filings and grants**




Years are based on September year-end.
Sources: *Performance & Accountability Report* (USPTO) and *Judicial Facts and Figures* (US Courts)

## Top damages awarded… and yet median jury damages trended lower

The largest patent-infringement verdict in US history was granted in 2016 in *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.* Idenix, a subsidiary of Merck, was awarded $2.5 billion by a jury for its patent related to a hepatitis C drug. While this award was remarkable, it appears as an outlier when viewed in the larger context: the 2016 median damages award was $6.1 million—a significant decrease from 2015's median award of $10.2 million.

*$2.5 billion awarded in largest patent infringement verdict in US history*

We also studied the top ten initial damages awards since 1997. It is important to note that the following awards are those identified during initial trial, and all have been vacated, remanded or reduced; were settled while pending appeal; or are still under appeal. In some cases, the settlement value exceeded the original trial verdict, generally because it covered post-trial sales beyond the initial litigation.

### Fig 2: Top ten largest initial adjudicated damages awards: 1997–2016

| Year | Plaintiff | Defendant | Technology | Award (in $M) |
|---|---|---|---|---|
| 2016 | Idenix Pharmaceuticals LLC | Gilead Sciences Inc. | Hepatitis C drugs | $2,540 |
| 2009 | Centocor Ortho Biotech Inc. | Abbott Laboratories | Arthritis drugs | $1,673 |
| 2007 | Lucent Technologies Inc. | Microsoft Corp. | MP3 technology | $1,538 |
| 2012 | Carnegie Mellon University | Marvell Technology Group | Noise reduction on circuits for disk drives | $1,169 |
| 2012 | Apple Inc. | Samsung Electronics Co. | Smartphone software | $1,049 |
| 2012 | Monsanto Company | E.I. Du Pont De Nemours and Co. | Genetically modified soybean seeds | $1,000 |
| 2005 | Cordis Corp. | Medtronic Vascular, Inc. | Vascular stents | $595 |
| 2015 | Smartflash LLC | Apple Inc. | Media storage | $533 |
| 2004 | Eolas Technologies Inc. | Microsoft Corp. | Internet browser | $521 |
| 2011 | Bruce N. Saffran M.D. | Johnson & Johnson | Drug-eluting stents | $482 |

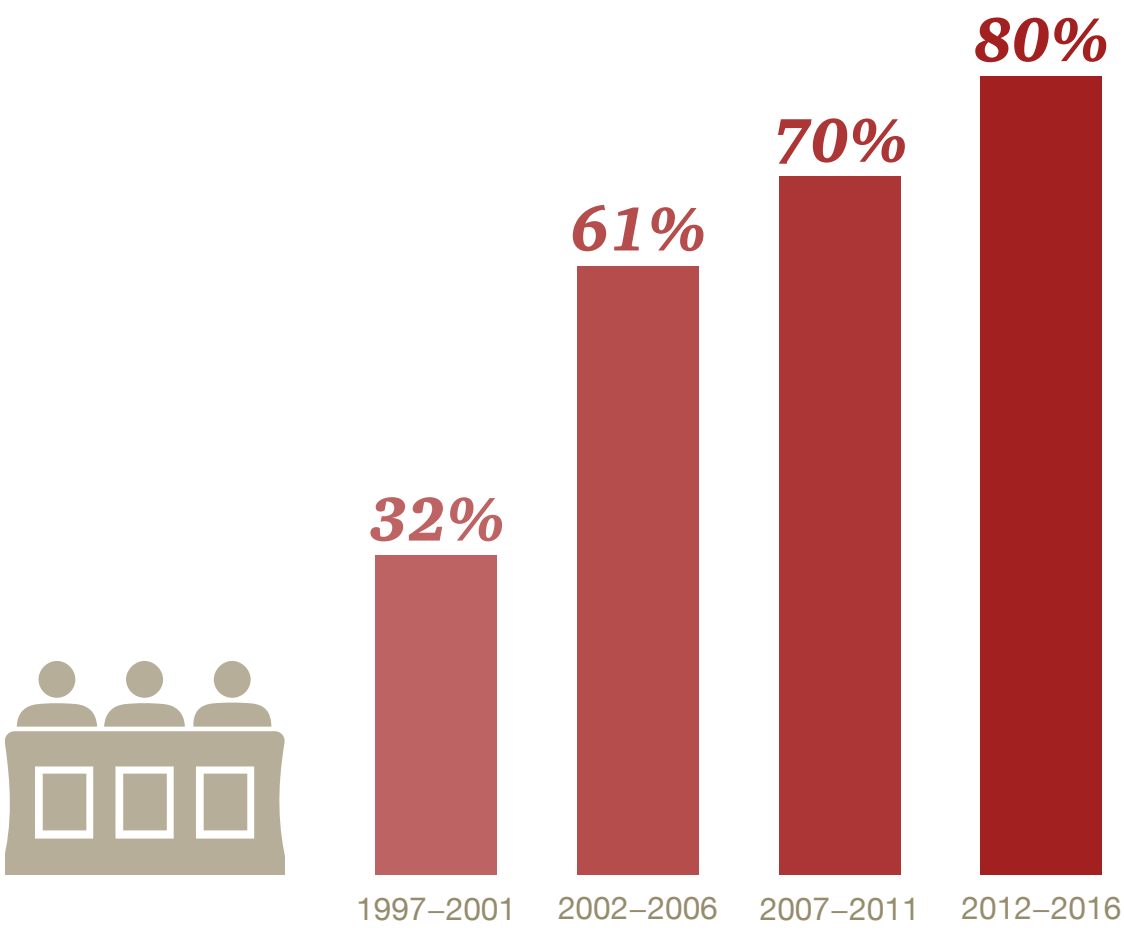
## Trier of fact: Will the shift to jury trials ever reach a ceiling?

We have witnessed a dramatic shift in the trier of fact in patent cases over the last 15 years.

Where previously bench trials were more common, since the turn of the century, jury trials have predominated: in the last five years, the percentage of cases decided by a jury—excluding Abbreviated New Drug Application (ANDA)-related cases[1]—reached 80%, from last year's Study's most recent five-year share.

The reason for the strong pull to jury trials is fairly straightforward: juries have historically tended to award patentees with higher success rates and median damages awards.

**Fig 3: Percent of cases decided by juries (excluding ANDA cases)**

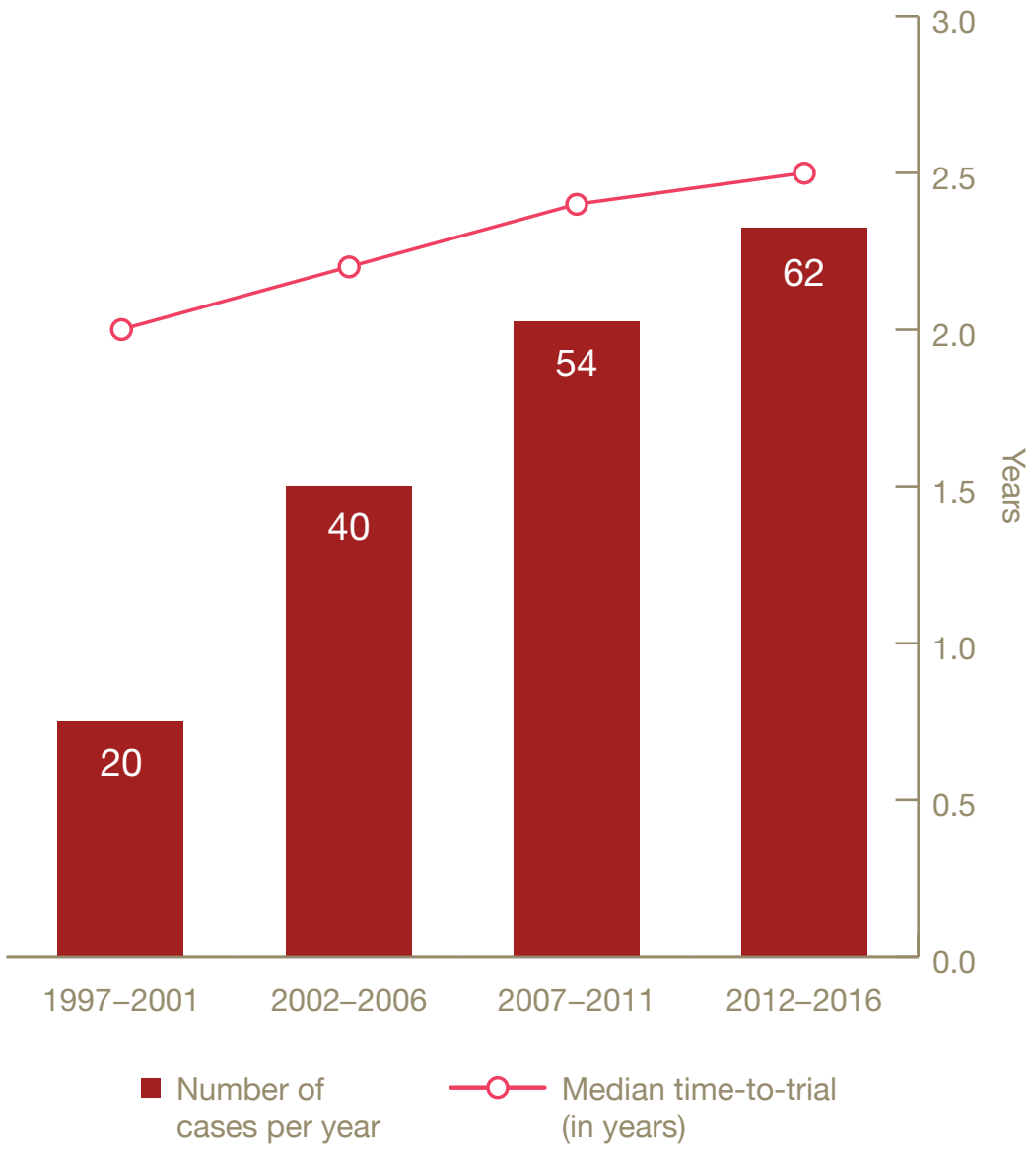



[1] These cases are, with rare exceptions, tried by the bench, and their increasing prevalence in recent years would otherwise skew this measure.

## General slowdown in time-to-trial

Despite the recent decline in number of patent cases filed, the amount of time parties must wait for trial has continued its slow growth towards 2.5 years.

**Fig 4: Median time-to-trial**




*Despite recent reductions in the number of litigations filed, the case volume has more than doubled over the study period. Additionally, detours through the Patent and Trial Appeal Board process are significantly up. Together these will continue to lengthen the median time to trial.*

## Expert witnesses: When business opportunities expose you to disputes

Business leaders are constantly making big decisions to drive growth and profitability: an acquisition, a new strategic alliance, outsourcing or other transaction. And any one of these opportunities can lead to a dispute.

Naturally, you want to minimize the chance of a dispute happening. But if it does, you want the right result for your company. And for that, chances are you'll need help with:

- Protecting the value of your intellectual property (IP), brand and business assets during a dispute
- Understanding the merits and potential magnitude of the dispute
- Gathering guidance on crucial industry, economics, finance and accounting issues

In complex business disputes, the outcome of your case (and even of your company) can rest on the quality and expertise of the professionals you turn to, in areas such as:

- Valuation (including IP and licensing matters)
- Advanced data analytics
- Quantification of damages
- Expert witness testimony
- Arbitration, mediation or special masters
- Forensic accounting

Whether your case centers on complex accounting issues, breach of contract, intellectual property infringement, business valuation, international arbitration or a range of other disputes, the right expert can help steer you through the controversy, present the facts to withstand vigorous cross-examination—and strengthen your chances of prevailing.

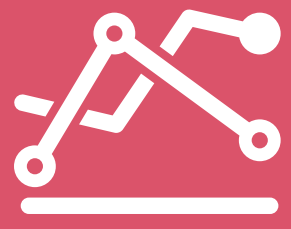
# *Damages:*
# Which way is up?

## Median damages award drops in 2016, while one case award hits record high

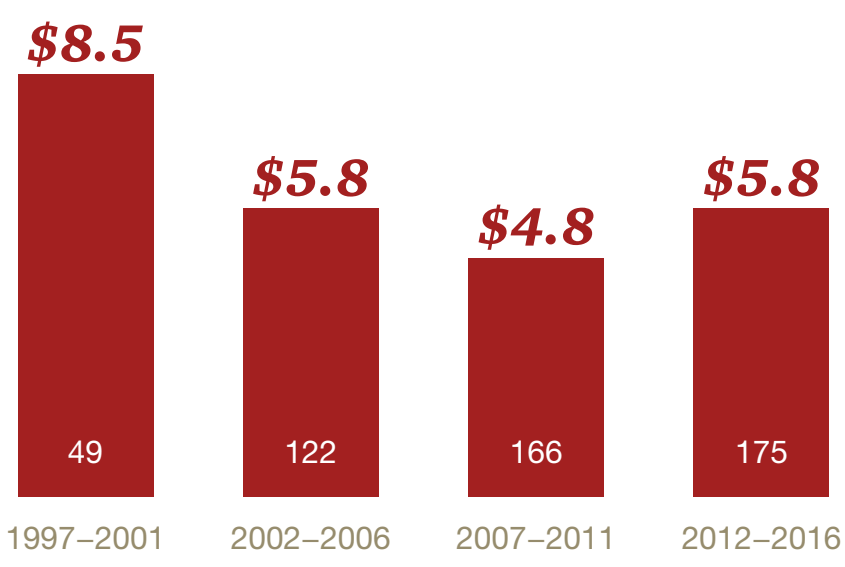
The annual median damages award between 1997 and 2016 ranged from $2.0 million to $17.0 million, with an overall median award of $5.8 million over the last 20 years. Despite the mega-award granted to Idenix, the median damages award was $6.1 million in 2016—a significant decrease from 2015's median award of $10.2 million.

Excluding damages awarded before trial (i.e., summary judgment and default judgment), the overall median award over the last 20 years jumps to $8.0 million.

*Despite the mega-damages awarded to Idenix, 2016 median damages award declined sharply from 2015*

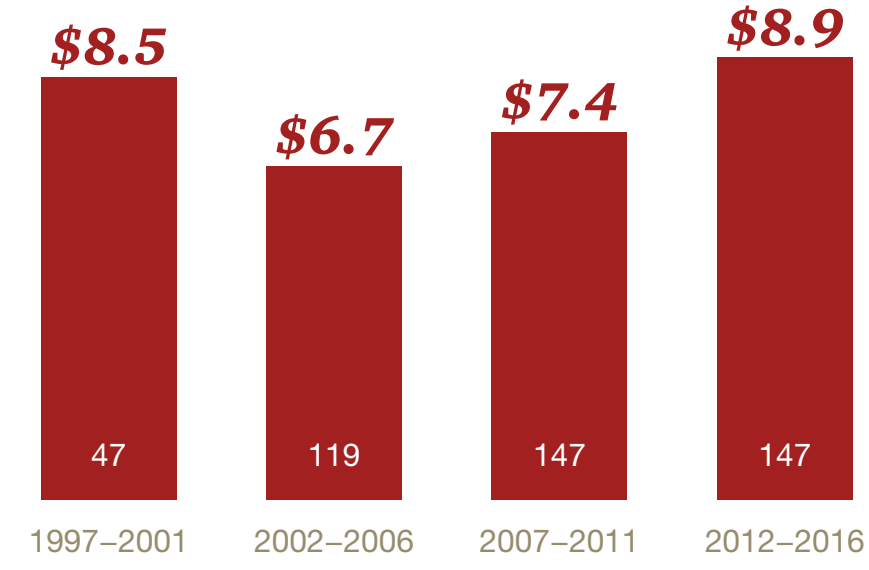


### Fig 5a: Median damages award (in $M)




The number of identified decisions is indicated within the respective column.

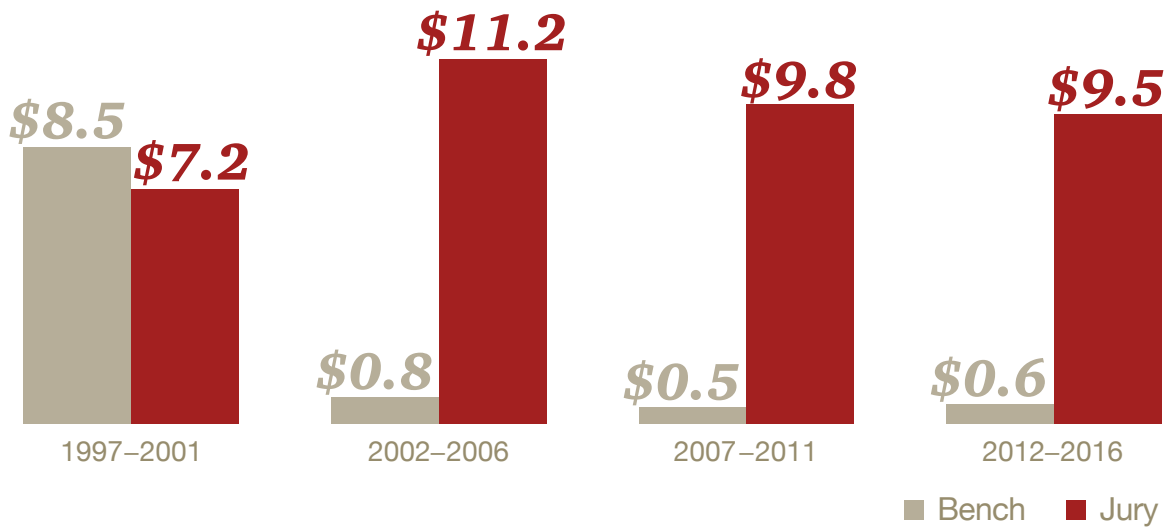
### Fig 5b: Median damages award (in $M) (excluding summary and default judgment)




The number of identified decisions is indicated within the respective column.

Despite significantly outpacing median bench awards (by a factor of 15 in the last five years), median jury awards have been steadily decreasing.

**Fig 6: Median damages award: bench vs. jury decisions (in $M)**




*Median jury award is 14x–20x greater than bench over the last 15 years*

## Winning enhanced damages gets a little easier

In June 2016, the US Supreme Court decided two cases jointly, concerning the hurdles for obtaining enhanced (up to 3x) damages under §284: *Halo v. Pulse* and *Stryker v. Zimmer.* This ruling overturned the Federal Circuit's 2007 *Seagate Technologies LLC* three-pronged test, instead directing that:

1. The "objective recklessness" requirement be eliminated, which previously allowed any plausible liability or infringement defense offered at trial (even if not considered by the accused at the time of infringement) to deflect willfulness claims.
2. The standard of proof should be relaxed to the preponderance of the evidence, rather than the previous higher bar of clear and convincing evidence.
3. *De novo* review for abuse of discretion was deemed unwarranted, thereby giving more deference to the district court's first impression on willfulness.

While the Court's guidance is still that enhanced damages should be limited to egregious cases of deliberate disregard of the patentee's IP rights, this ruling will nevertheless make obtaining them a bit less daunting.

## Reasonable royalties vs. lost profits

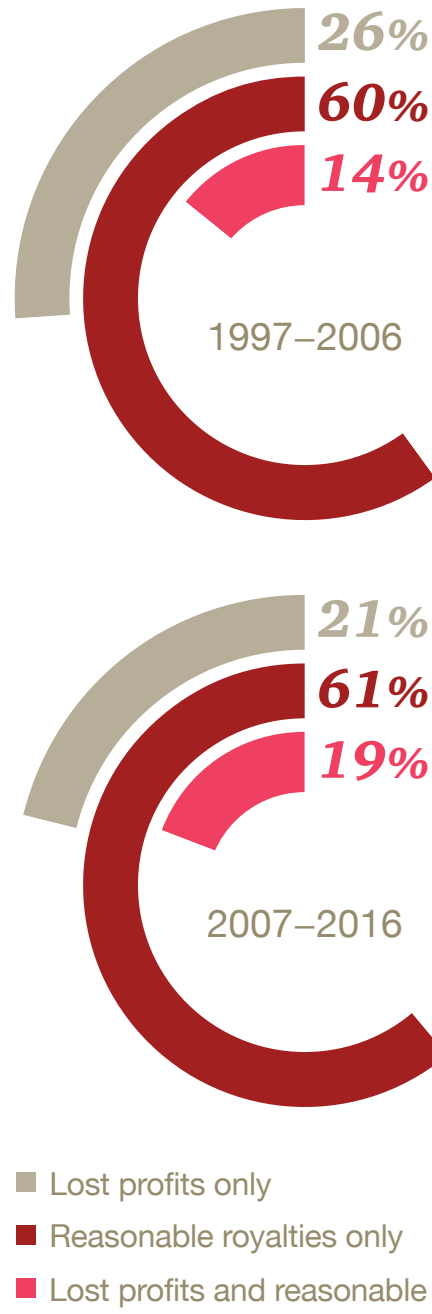
*How are patent holders most often compensated for infringement?*

Among practicing entities, reasonable-royalty-only awards are still the type of damages most frequently awarded in patent cases—almost three times as often as lost-profits-only awards. Hybrid awards, where both lost profits and reasonable royalties are awarded together, are less often awarded.

So why the strong preference for reasonable royalties over lost profits? The main reasons:

- 21% of our identified cases involve NPEs, which are ineligible for lost profits damages.
- Even patentees eligible for lost profits awards might eschew lost profits claims—they may not want to risk disclosing the proprietary cost and profit information necessary for the calculation of lost profits.
- Lost profits entitlement can be more difficult to establish. As the proliferation of competition and specialized distribution channels disrupts many industries (pharmaceutical, consumer products), there is greater access to substitute products. Therefore, even without an alleged infringer's products on the market, consumers may not have purchased the patentee's covered product.

**Fig 7: Composition of damages awards (practicing entities only)**



## *Apple v. Samsung:* Supreme Court Weighs in on Design Patents

Design patent damages have been a hot topic of discussion since August 2012, when a California jury awarded Apple significant damages in its lawsuit against Samsung—with a large portion of the damages based on Samsung's entire profits on accused smartphones. At issue is the difference between damages law for infringement of design patents (35 U.S. Code § 289) versus other patents (35 U.S. Code § 284).

In a unanimous 8-0 decision, the Supreme Court reversed the Federal Circuit and threw out Apple's nearly $400 million in damages. The case went back to District Court, after the Federal Circuit remanded it for further consideration of what damages are appropriate in light of the Supreme Court's decision. This will likely necessitate a third trial in the ongoing *Apple v. Samsung* saga.

### *Design patents and available damages*

According to the US Patent and Trademark Office (USPTO), the claimed subject matter of a design patent is the *design* embodied in or applied to an article of manufacture (or portion thereof)—and not the article itself. The design consists of the visual characteristics embodied in or applied to an article.

A patentee claiming infringement of a design patent can recover damages under § 284 or § 289. Traditionally better known, § 284 calls for actual damages suffered by the patent holder (e.g., lost profits, price erosion) but not less than a reasonable royalty to compensate for infringement. Critically, damages under § 284 require an apportionment between the patented invention and other components, unless the patented element drives the sale of the entire apparatus—including unpatented components—and hence qualifies for the "entire market value rule".

In contrast, § 289 allows for a design patent holder to claim the infringer's entire profits as damages. Prior to the Supreme Court's ruling, District Court and Federal Circuit decisions interpreted the language under § 289 to include the entirety of an infringer's profits, even if the design patent only relates to one component among many others.

*What did the Court say? Apportionment is likely on its way*

The Supreme Court held that for "a multicomponent product, the relevant 'article of manufacture' for arriving at a § 289 damages award need not be the end product sold to the consumer but may be only a component of that product." This seemingly aligns § 284 and § 289 damages, suggesting the requirement of apportionment of damages to the relevant patented and unpatented components.

The question in the *Apple v. Samsung* matter remains, however: what is the "article of manufacture" in the context of the design patents involved? These issues still need to be resolved and will be taken up by the District Court on remand.

*Design patent growth and the road ahead*

Interestingly, USPTO data shows that since the first *Apple v. Samsung* jury award in 2012, both design patent applications and design patents issued are growing at a faster rate than other patents. Between October 2012 and September 2016, design patent applications grew by a compound annual growth rate of 7.4% (compared to 4.6% for other patents). Similarly, issuances of design patents outpaced other patents (4.8% for design patents versus 2.5% for other patents) over the same time period.

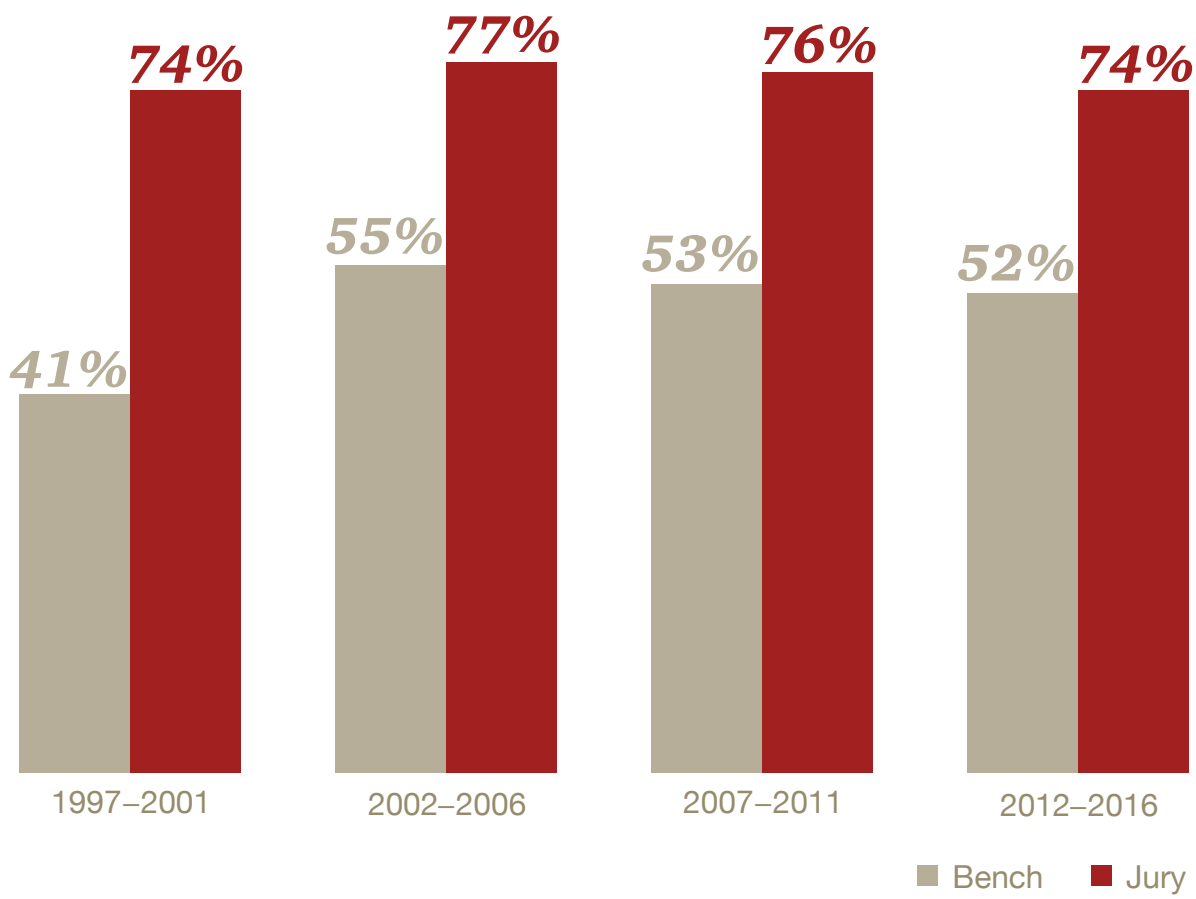
Is the recent uptick in design patent activity related to the *Apple v. Samsung* litigation, in that it brought attention to the broader design patent remedies available? Will we continue to see similar trends? Or will the effect of the Supreme Court decision to align damages be to cool off design patent filings? We shall see…

# *Success rates:*
# How are jury and bench trials faring?

## Success rates decline modestly, while gap remains large

Over the last 20 years, patent holders have enjoyed 22–33% higher trial success rates with juries than with the bench. However, success rates for both the bench and juries have declined slightly over the most recent 15 years.

**Fig 8: Trial success rates: bench vs. jury**




*Patentees' success rates with juries are substantially higher than with the bench. This success gap is even more pronounced for non-practicing entities (NPEs).*

## Success rates are significantly higher at trial than summary judgment

Over the last 20 years, practicing entities fared better than NPEs, enjoying an 11% premium in their overall success rate. However, the gap in success rates narrows at trial as compared to summary judgment.

## Practicing entities are more successful than NPEs, especially with the bench

While overall success rates increase for both practicing entities and NPEs at trial, it is highly dependent on the trier of fact. The jury gives much higher success rates compared to the bench: almost double for NPEs and 1.5x for practicing entities.

**Fig 9: Patent holder success rates: 1997–2016**

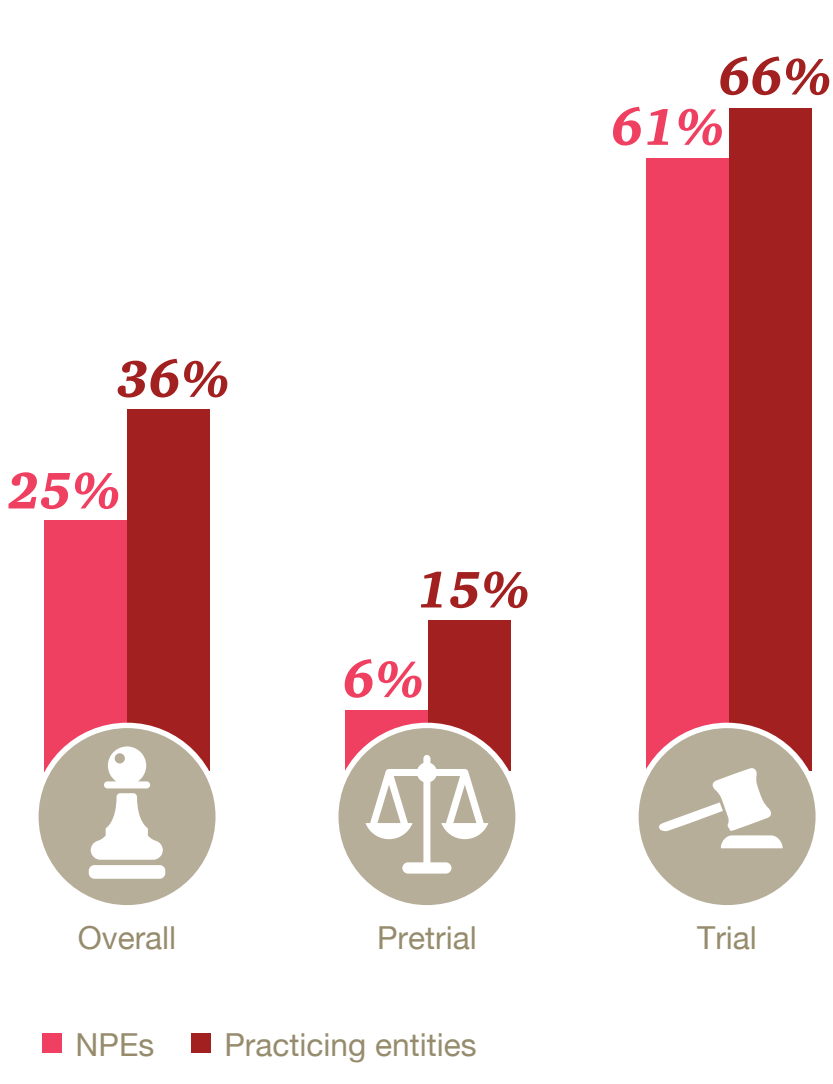
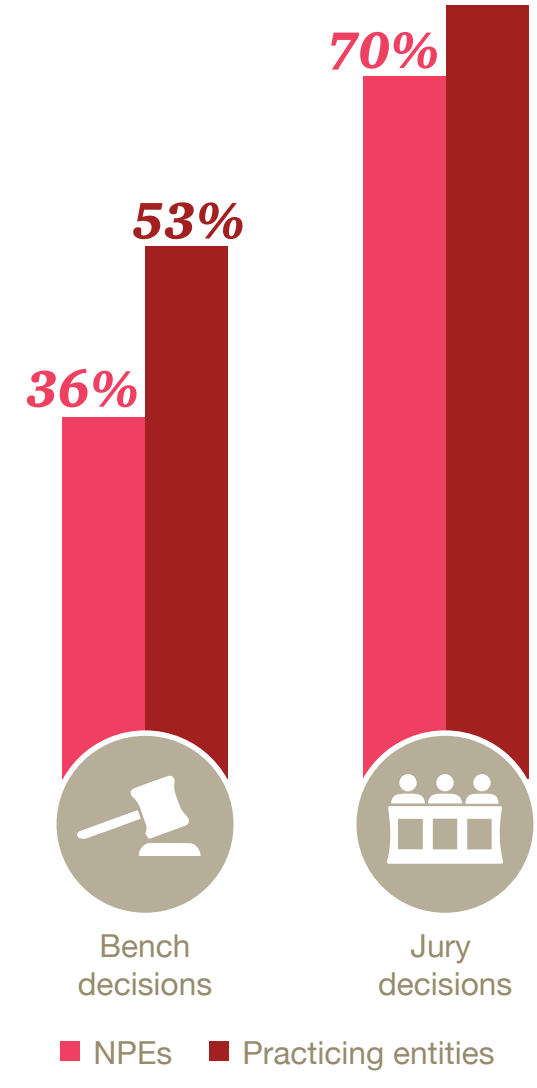



**Fig 10: Patent holder success rates at trial: 1997–2016**



# *Practicing entities and NPEs:* Where's the gap?

## Disparity between NPE and practicing entity damages grows wider

Our analysis shows the continuation of a trend that began in the early 2000s: significantly higher damages awarded to NPEs relative to practicing entities. The median damages award for NPEs was significantly higher than practicing entities in the last 15 years. While this disparity had narrowed to about 1.6x in the 2007–2011 period, in the most recent five-year period the NPE median damages award climbed to 3.8x the median for practicing entities.

*Damages awards are almost*

***4x***

*greater for NPEs*

**Fig 11: Median damages award: NPEs vs. practicing entities (in $M)**

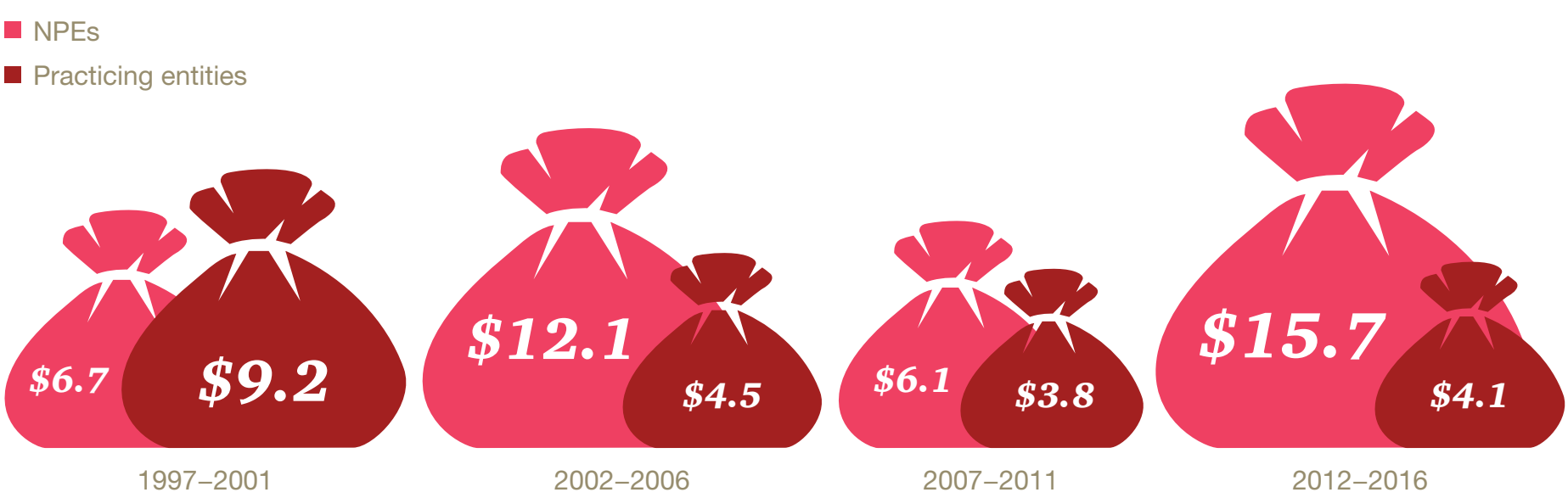
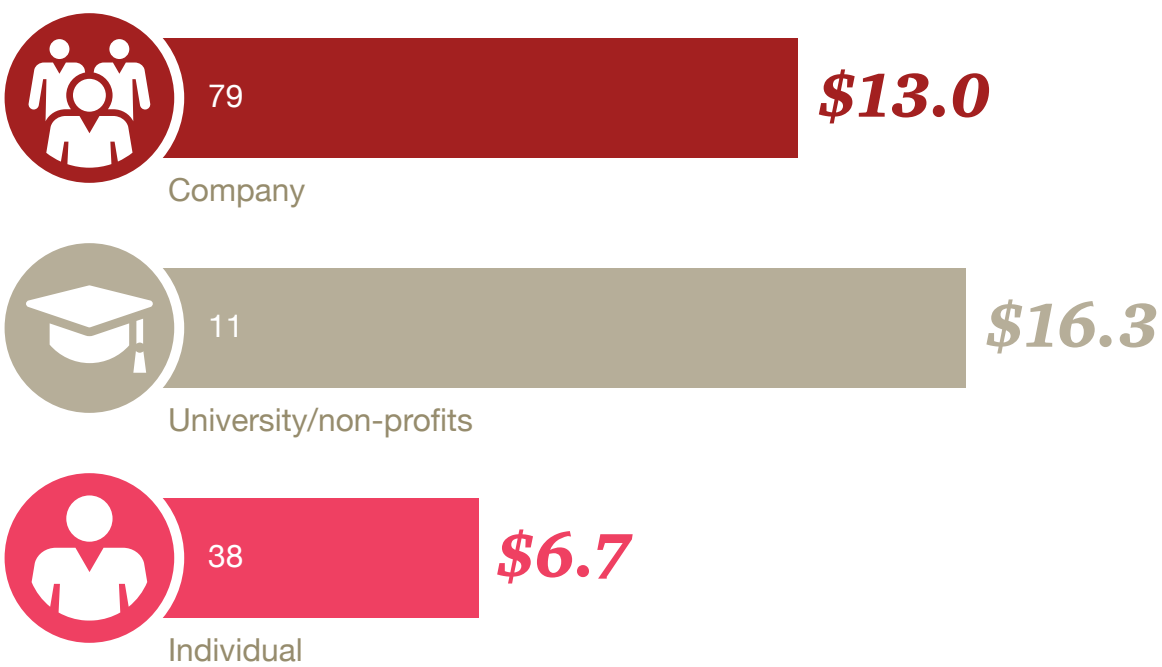



**Fig 12: Key statistics for practicing entities and NPEs: 1997–2016**

| | Median time-to-trial (in years) | Overall success rate | Median damages award |
|---|---|---|---|
| NPEs | 2.6 | 25% | $11,466,676 |
| Practicing entities | 2.3 | 36% | $4,923,580 |

We looked further into NPE litigation by NPE type. We compared companies, universities/non-profits, and individual inventors.

**Fig 13: Patent holder median damages award by NPE type: 1997–2016 (in $M)**




*Universities/ non-profits do not litigate as often as other NPE types; however, when they do, they have both higher success rates and higher median damages.*

The number of cases is indicated within the respective row.

Universities/non-profits still lead in both median damages award and overall success rate, although they comprise the smallest share of NPE cases.

**Fig 14: Patent holder success rates by NPE type: 1997–2016**

79/283

**28%**

Company success rate falls in the middle

11/21

**52%**

Universities/non-profits lead the pack in overall success rate

38/213

**18%**

Individual NPEs lag far behind, below the overall 25% success rate for NPEs

The number of cases is indicated below each graphic.

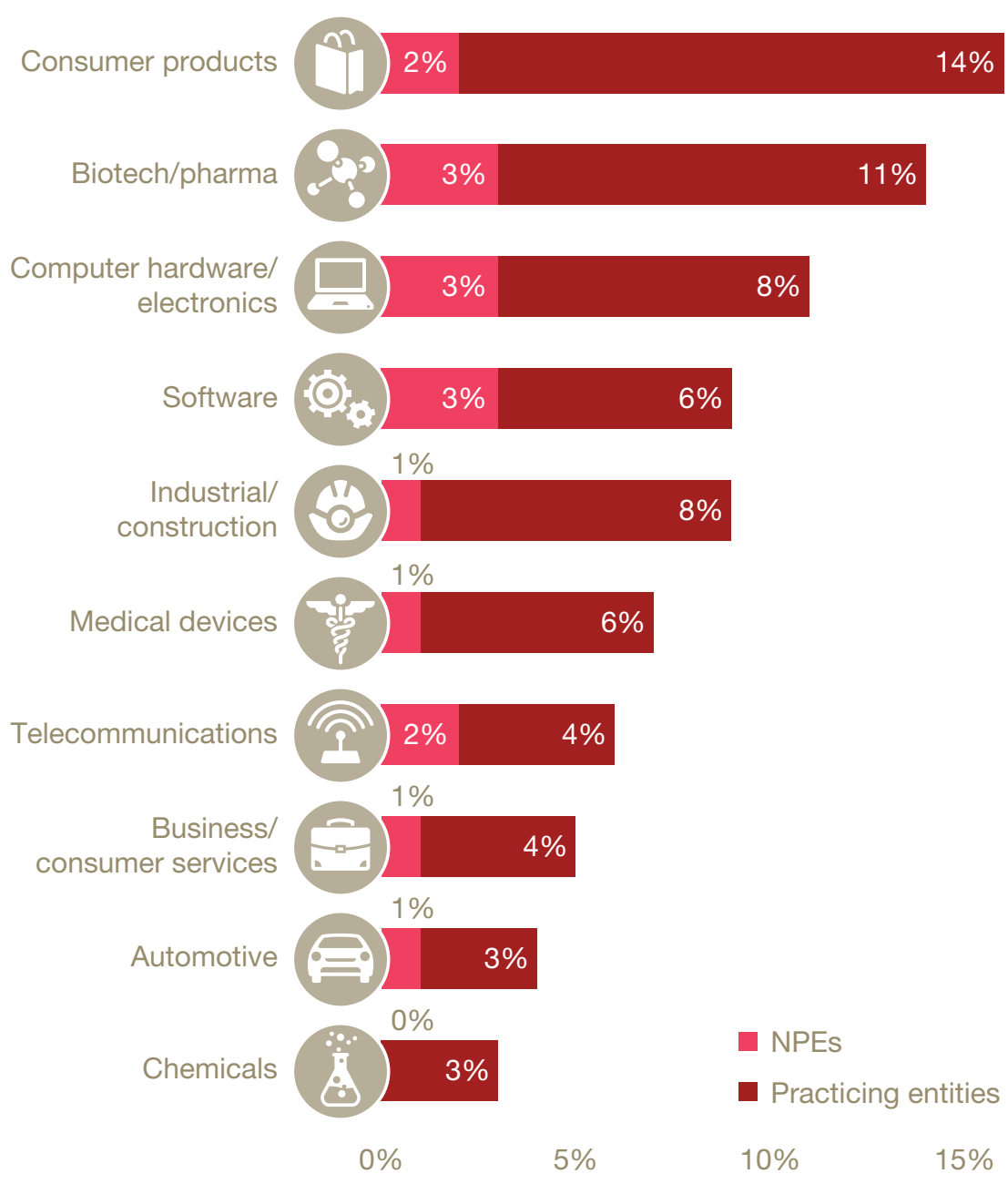
# *Industries:*
# Which ones are leading the pack?

The five most active industry classifications (out of 20) collectively account for 60% of identified decisions. Patent cases associated with the consumer products industry continue to be most prevalent, relating to products such as:

- diapers
- infant carriers
- cosmetic palettes
- coffee cartridges

***Since 1997, consumer products represented 16% of all identified patent cases***

**Fig 15: Distribution of cases: top ten industries: 1997–2016**

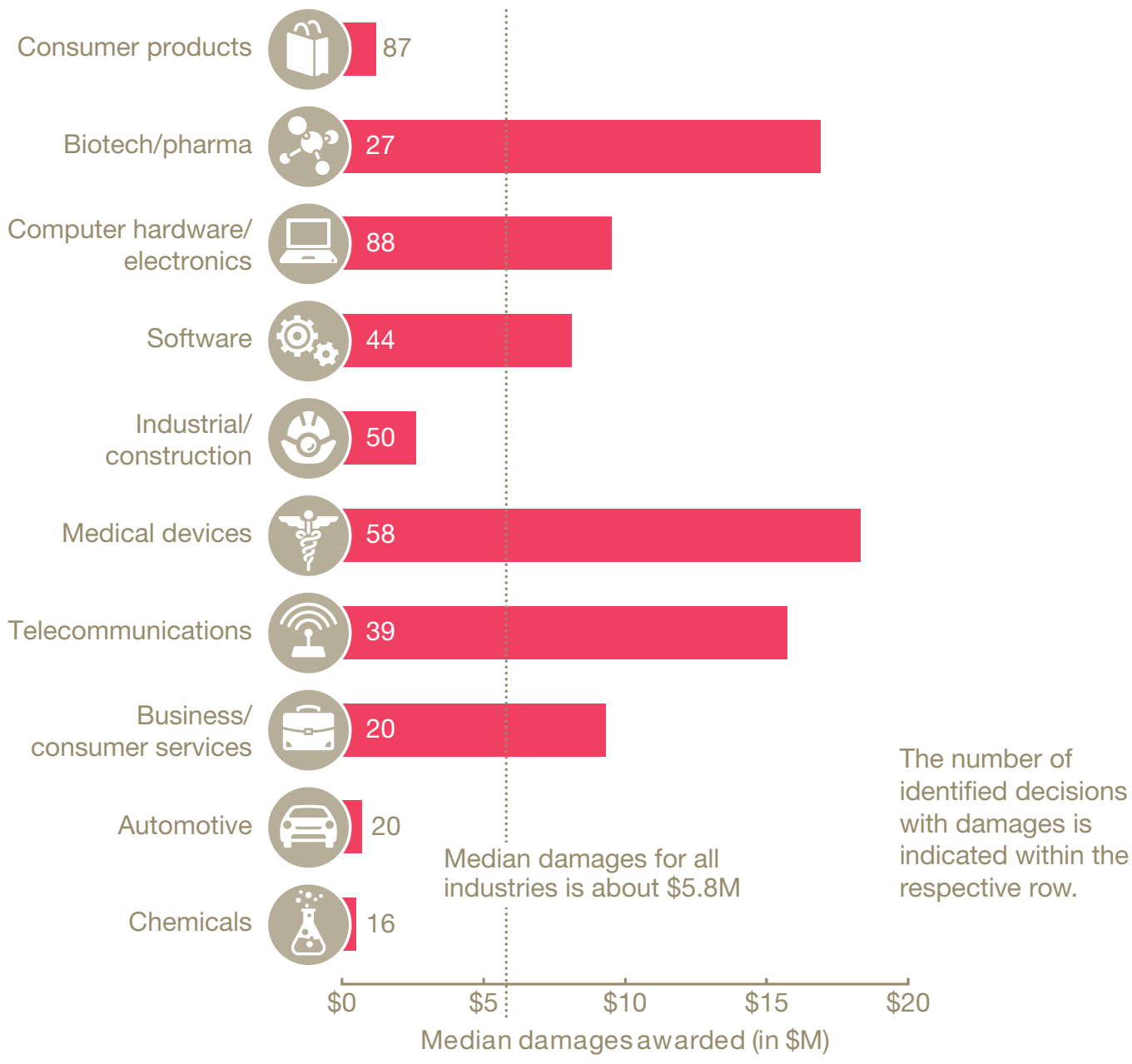


Although patents associated with the consumer products industry represented the largest percentage of identified decisions, their median damages award was among the lowest of all industries.

In a change, the medical device industry surpassed biotech/pharma (the longtime leader) for highest median damages. Along with telecommunications, these industries continue to experience significantly higher median damages awards than other industries. These industries tend to include capital-intensive businesses that require significant research and development or technology infrastructure. They also entail generally higher sales and margins, which translates to larger damages.

*Medical devices take the #1 spot for highest median damages award*

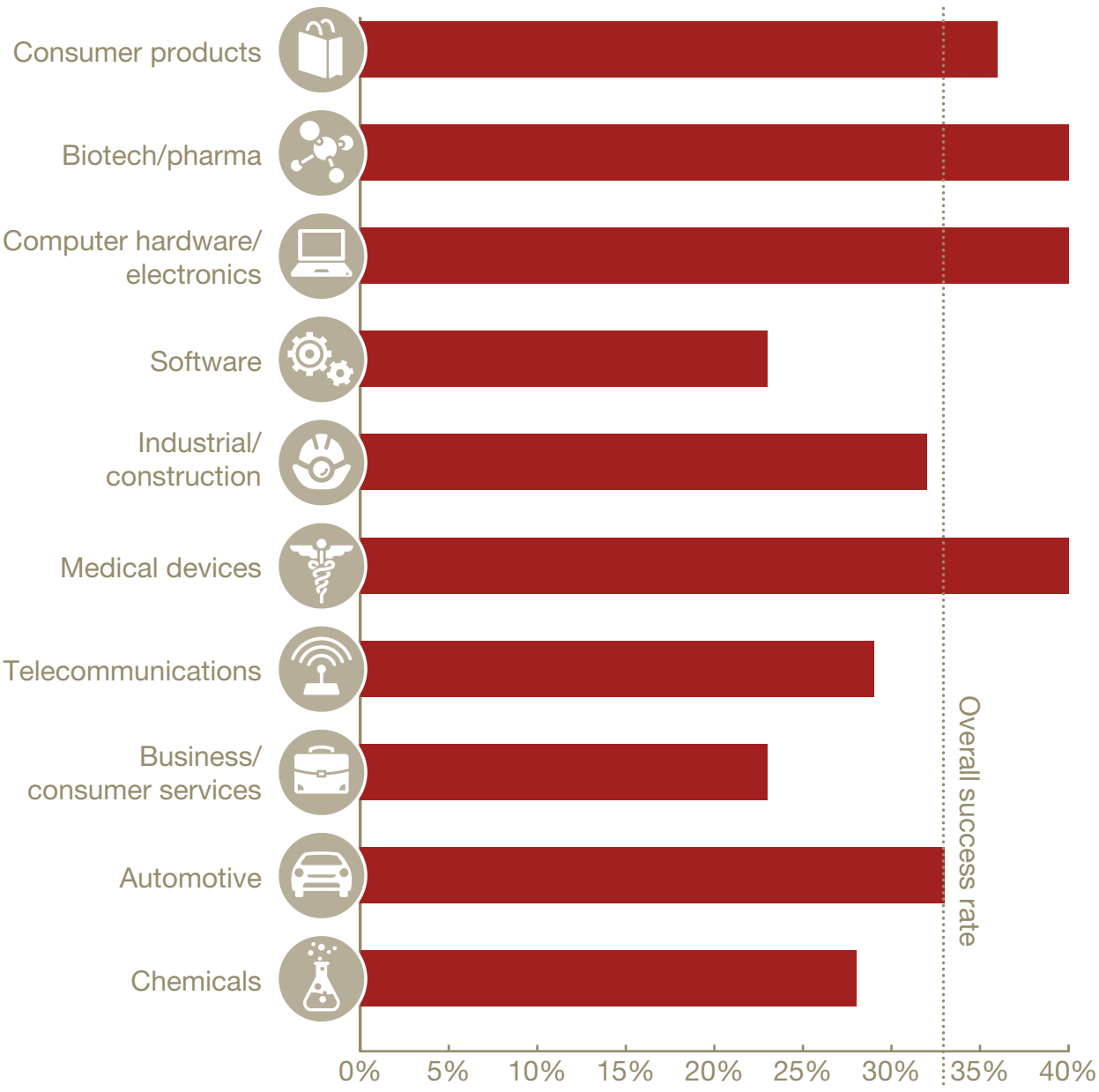
**Fig 16: Median damages award: top ten industries: 1997–2016**



## Success rates fairly consistent across industries, with notable outliers

Holders of patents related to the consumer products, biotech/pharma, computer hardware/electronics and medical devices industries achieved success rates slightly higher than the median of 33%. Software and business/consumer services were notable outliers, with significantly lower success rates.

### Fig 17: Patent holder success rates: top ten industries: 1997–2016




## How well are you protecting your IP, brand and reputation?

The conditions that surround your intellectual property, your brand and your reputation are increasingly treacherous. Counterfeit and pirated goods are entering countries from air, land and sea, infiltrating legitimate supply chains and exceeding the ability of brands to deal with them adequately. Cyber attacks—threatening both your IP and your reputation—are a threat that seems to grow by the day. Online media is a game-changer as a major conduit for collecting and disseminating information—be it accurate, inaccurate or malicious.

And economic crime continues unabated. Thirty-eight percent of US companies say they've been victimized by fraud over the last 24 months—with 64% saying that the primary impact of the crime was on the strength of their brand and reputation. What's more, one in four expect to experience intellectual property infringement in the next two years.[2]

In the face of this complex of threats, how do you protect your brand and IP?

Many leading companies are turning to global intelligence to monitor risks, opportunities and dangers emerging via social media, online communities, news sites and dark webs. They're also using these tools to assess public sentiment and brand perception to uncover potential blind spots. Global intelligence can help you answer critical questions such as:

- What are your customers and competitors saying about you?
- Who are key influencers and drivers of the conversation around your brand integrity?
- How should you flag adverse posts such as potential risks and threats to your reputation?
- How is the public responding to your brand, and how can you react?
- What threat actors are going undetected?
- How will foreign political risk affect your organization?

To learn how PwC can help you leverage global intelligence to protect your reputation and safeguard your assets, click ***here***.

[2] Source: PwC's Global Economic Crime Survey 2016. PwC, 2016.

# *Across districts:*
## Results may vary?

**Fig 18: District Court rankings: 1997–2016**

| Overall rank | District | Case Count | Rank | Overall success rate | Rank | Median damages award | Rank | Median time-to-trial (in years) | Rank |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Delaware | 285 | 1 | 41% | 4 | $16,162,113 | 4 | 2.1 | 5 |
| 2 | Texas Eastern | 195 | 3 | 54% | 1 | $9,948,569 | 5 | 2.2 | 8 |
| 3 | Virginia Eastern | 59 | 9 | 29% | 11 | $32,684,334 | 2 | 1.0 | 1 |
| 4 | Wisconsin Western | 44 | 12 | 39% | 5 | $8,005,377 | 6 | 1.2 | 2 |
| 5 | New Jersey | 110 | 6 | 38% | 6 | $16,164,179 | 3 | 2.7 | 13 |
| 6 | Florida Middle | 46 | 11 | 50% | 2 | $497,782 | 15 | 1.9 | 3 |
| 7 | Texas Southern | 56 | 10 | 23% | 14 | $58,075,564 | 1 | 2.1 | 7 |
| 8 | California Northern | 216 | 2 | 27% | 12 | $5,402,099 | 9 | 2.6 | 12 |
| 9 | Texas Northern | 43 | 13 | 47% | 3 | $4,793,384 | 10 | 2.4 | 10 |
| 10 | Massachusetts | 82 | 8 | 33% | 7 | $7,268,728 | 7 | 3.5 | 14 |
| 11 | Florida Southern | 43 | 13 | 30% | 8 | $3,084,469 | 11 | 2.1 | 6 |
| 12 | New York Southern | 140 | 5 | 29% | 9 | $2,217,004 | 13 | 2.5 | 11 |
| 13 | California Central | 110 | 6 | 26% | 13 | $3,066,008 | 12 | 2.3 | 9 |
| 14 | Illinois Northern | 154 | 4 | 21% | 15 | $6,086,198 | 8 | 3.7 | 15 |
| 15 | California Southern | 41 | 15 | 29% | 10 | $1,953,464 | 14 | 1.9 | 4 |
| | Overall (all decisions identified) | 2,446 | | 33% | | $5,783,407 | | 2.4 | |

The overall ranks for these courts are based on their relative ranking for each of the four measures, equally weighted.

## TC Heartland: The end of “venue shopping” as we know it

*On May 22, 2017, the Supreme Court released its decision in TC Heartland, ruling that patent infringement cases can only be filed in the jurisdiction where the accused infringer is incorporated.*

*What happened?*

In January 2014, Kraft Foods Group accused Indiana-based TC Heartland of infringing Kraft’s patents for low-calorie sweetener dispensers. Kraft filed the suit in Delaware, but Heartland filed a motion to either dismiss the action or transfer venue to the Southern District of Indiana (where Heartland is headquartered). Heartland argued that it had no local presence in Delaware, and it does not actively seek business in Delaware. However, evidence established that Heartland shipped orders of the accused products into Delaware under contracts with two national accounts.

Both the Delaware District Court and the Federal Circuit rejected Heartland’s theory that it did not “reside” in Delaware for venue purposes. They also rejected the contention that the court in Delaware lacked specific personal jurisdiction, essentially affirming the long standing interpretations of 28 U.S.C. §§ 1391 and 1400(b), which hinge on the defendant’s residence in the district and/or that the defendant has committed acts of infringement in the district (e.g., sold the alleged infringing product in the district).

On May 22, 2017, the Supreme Court released its unanimous decision, ruling that patent infringement cases can only be filed in the jurisdiction where the accused infringer is incorporated, effectively ending the practice of “venue shopping.”

*What can we expect?*

This profound reapportionment of new cases will have significant and long-lasting consequences on the patent litigation landscape as we’ve come to know it, in terms of patent holder litigation strategy and success measures.

In the wake of the Supreme Court’s decision, we expect to see even more patent cases filed in Delaware, the leading state of incorporation for U.S. companies. The Eastern

Across districts

District of Texas, which has become the favored choice of venue with almost 40% of new cases filed there last year, will virtually disappear overnight as a destination for new patent cases.

If historical trends for district courts prevail, we believe we will generally see patentee success rates and median damages decline. The districts that will now attract more litigation (e.g., Delaware, California, Illinois, New Jersey, New York) have historically shown lower success rates than the Eastern District of Texas. Most of these districts, particularly California, have demonstrated lower median damages. Still, the District Court of Delaware, which almost certainly will widen its lead as the most popular venue for patent litigation, ranks relatively highly in both patentee success rates and median damages.

Since NPEs and other patentees may be less likely to file infringement lawsuits in the future, given less-attractive venue options, we will also likely see the total number of new patent cases – already on a downswing since 2013 – continue to decline.

Cases with NPEs as patent holders are concentrated in a few districts. Out of 94 total districts, the five with the most identified decisions involving NPEs accounted for 46% of all such decisions—and the top ten districts accounted for 60%. The most active NPE districts remained consistent, indicating steady concentration of NPE cases in certain courts.

But the data does not point to a clear correlation between number of identified NPE decisions in a district and relative NPE success rates. Texas Eastern, with the most identified NPE cases by far, also has one of the highest success rates—almost double the NPE average. Delaware, with the second-most identified NPE cases, has success rates in line with the NPE average. However, the next three districts in NPE case counts yielded significantly lower success rates than the NPE average.

***NPEs continue to strongly favor the Eastern District of Texas, where NPE success rates almost double the NPE average.***

**Fig 19: District courts with most identified decisions with NPE as patent holder: 1997–2016**

| District | Decisions involving NPEs | Total identified decisions | NPE % of total decisions | NPE success rate |
|---|---|---|---|---|
| Texas Eastern | 74 | 195 | 38% | 49% |
| Delaware | 45 | 285 | 16% | 27% |
| California Northern | 44 | 216 | 20% | 14% |
| Illinois Northern | 42 | 154 | 27% | 12% |
| New York Southern | 31 | 140 | 22% | 16% |
| California Central | 24 | 110 | 22% | 29% |
| Massachusetts | 14 | 82 | 17% | 36% |
| Texas Northern | 13 | 43 | 30% | 69% |
| Texas Southern | 12 | 56 | 21% | 8% |
| Virginia Eastern | 12 | 59 | 20% | 17% |
| Florida Southern | 11 | 43 | 26% | 9% |
| Florida Middle | 11 | 46 | 24% | 55% |
| New Jersey | 10 | 110 | 9% | 30% |
| All identified decisions | 517 | 2,446 | 21% | 25% |

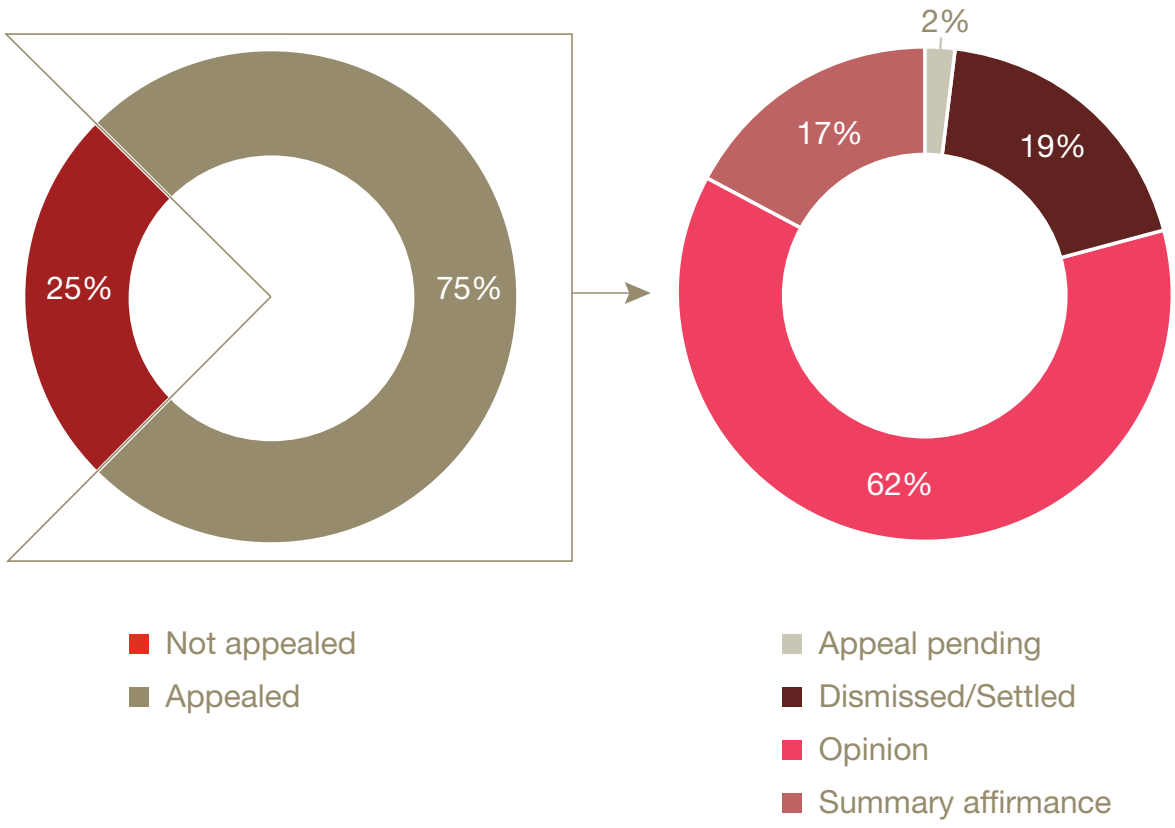
Includes districts with at least 10 identified decisions involving an NPE as the patent holder.

# What becomes of patent cases after appeal?

Our analysis of appellate outcomes in patent litigations from the Federal Circuit captures district court decisions originally tried between 2006 and 2014. This scope of research examined 526 cases from the district courts in those nine years. We selected this period to ensure that the majority of cases appealed had reached a conclusion at the Federal Circuit. We then researched the appellate status of such cases through December 2016.

Three quarters of the cases we analyzed were appealed—with more than half of the appeals having reached a conclusion in the form of an opinion. This underscores the Federal Circuit's powerful impact on patent trial decisions.

**Fig 20: Status of district court cases: 2006–2014 decisions**




*Be careful what you wish for: 75% of decisions are appealed—and more than half of appeals overturn one or more aspects of the lower court's decision.*

## Both winners and losers continue to appeal to the Federal Circuit

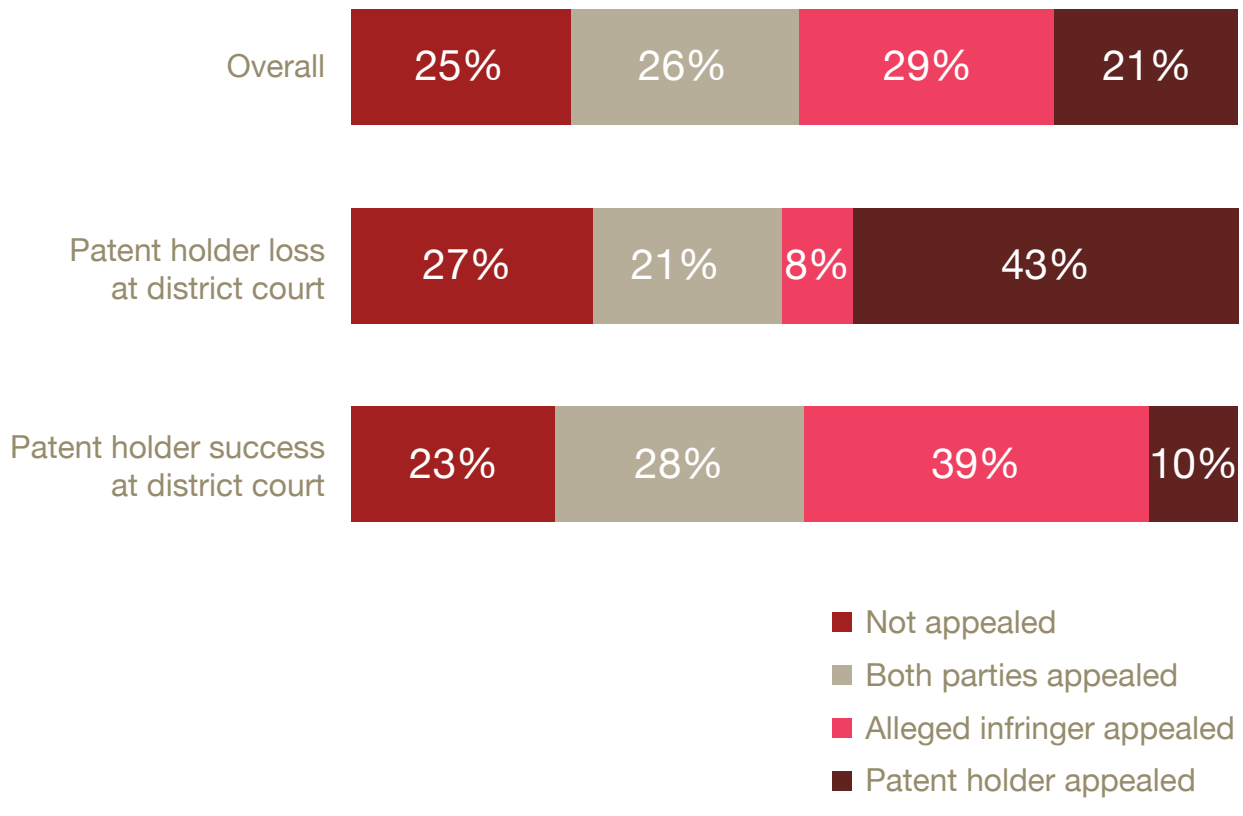
Our study found that post-trial, the alleged infringer appeals more often overall (29% individually) than the patent holder (21% individually). Patent holders win more often at trial (66% trial win rate in 2006–2016), and thus have less reason to appeal than the losing party.

The perspective of who won and who lost at trial gives a more nuanced view of frequency of appeals by side.

- **"Losers"** Based on our data, losing patent holders appeal more often (43% individually) than losing alleged infringers (39% individually).
- **"Winners"** Ten percent of successful patent holders and eight percent of successful alleged infringers appeal individually. This demonstrates that even a favorable outcome at the district court can leave a party not fully satisfied—whether on issues involving the patent claims, product and territory coverage, damages awarded, pre-/post-judgment interest, enhanced damages, or permanent injunction.

*Overall, 26% of district court cases were appealed by both parties.*

### Fig 21: Appeals after district court decisions: 2006–2014



## Appellate outcomes: a mixed bag

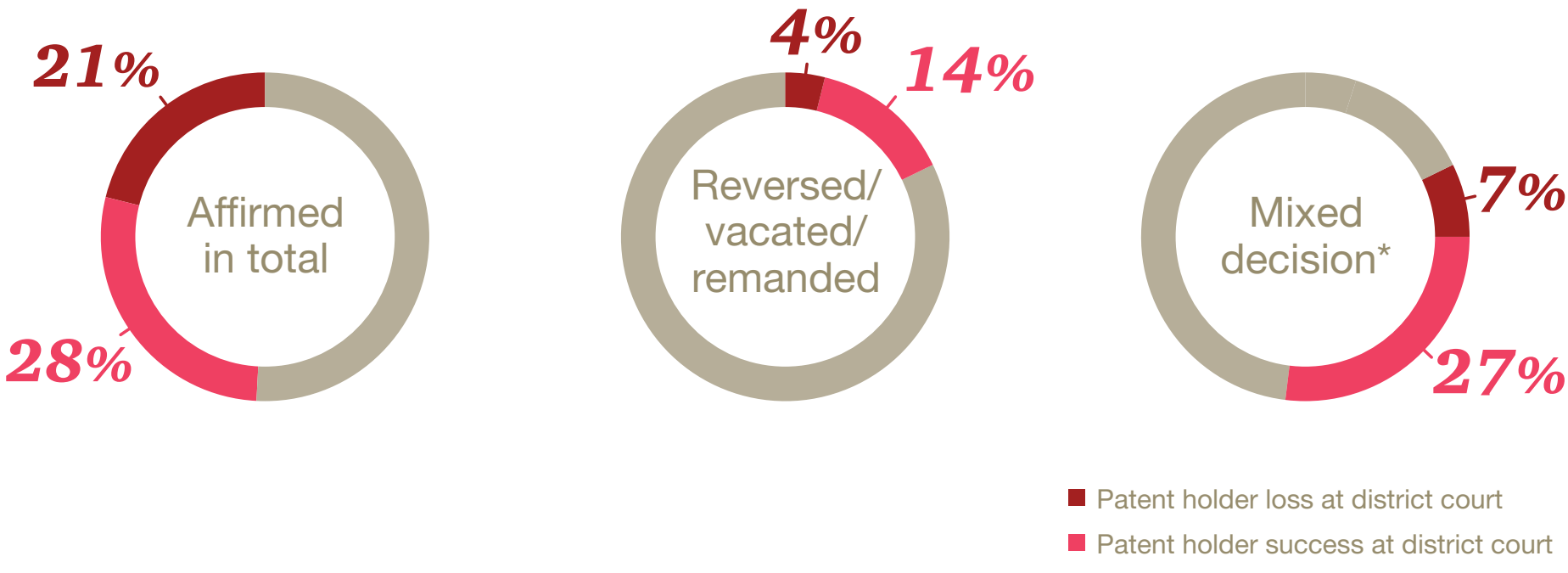
Our analysis shows that fewer than half of appealed patent infringement cases were affirmed, while 18% were entirely reversed, vacated and/or remanded. And 34% of appeals yielded mixed decisions, where some aspects of the appeal were affirmed while others were reversed, remanded or vacated.

However, the likelihood of any given appeal outcome varies according to which party won or lost the initial district court case.

**52%**

of appealed cases are ***modified*** in some regard

**Fig 22: Appeal outcome by success of patent holder in district court: 2006–2014**




(*) Mixed decisions are decisions in which the appeal was both affirmed in part and reversed, vacated or remanded in part. Percents add to greater than 100 due to rounding.

## Forensic Technology Solutions: Enabling faster, more efficient, more strategic case review

For this year's report, we departed from our traditional manual review method and used our technology team for help in redesigning our process. As a direct outcome, we have enhanced our research methodologies and workflows, which has proved to be significantly faster and more efficient.

A successful patent litigation case requires significant research legwork in case retrieval, review and analysis, as is the case with this study. Broadly speaking, that workload can be divided into two segments:

- **Structured data.** Reviewing all patent litigation decisions, and extracting and filtering the basic data—judge, court, year, type, industry, subject matter—for relevant data points.
- **Unstructured data.** Zeroing in on and analyzing more nuanced information needed to inform a legal strategy.

Traditionally for this study, both layers of review have had to be accomplished manually—not only a time-consuming task, but one prone to errors requiring many layers of review. This year we leveraged robust new technology tools that simplified and improved the quality, speed and accuracy of the review, saving time and money in the process.

PwC's document processing tools and techniques helped us extract metadata from judgments, index their content and categorize the judgments to streamline review, stratify them into multi-level review teams, and even create a custom content-extraction program to collect additional document metadata as needed.

This technology also helped us to manage the review process—from first capture to comments from subsequent readers and reviewers—creating an audit trail, while enabling greater efficiency and transparency.

Learn more about PwC's Forensics Technology Solutions by visiting *www.pwc.com/us/forensics*

# Methodology

To study the trends related to patent decisions, PwC identified final decisions at summary judgment and trial recorded in two Lexis Advance databases, US District Court Cases and Jury Verdicts and Settlements, as well as in corresponding docket entries from LexisNexis CourtLink.

The study identified 2,446 district court patent decisions issued since 1997. Some figures cited in this study have been rounded, therefore totals may not equal the sum of their components.

Definitions for important terms used throughout the study are listed here:

- **Cases decided at summary judgment** include those district court patent infringement cases where a judge has issued a dispositive opinion regarding invalidity and/or infringement at summary judgment.
- **Cases decided at trial** include those district court patent infringement cases where a decision was rendered by a judge or jury after trial.
- **Successes** are instances where a liability decision was made in favor of the patent holder.
- **Time-to-trial** is calculated from the complaint date to the first day of either the bench or jury trial for each case.
- A **nonpracticing entity (NPE)** is an entity that does not have the capability to design, manufacture, or distribute products with features protected by the patent.
- **Median damages** have been adjusted for inflation to 2016 US dollars.

## Want to know more?

From the boardroom to the courtroom, success is often predicated on the depth and credibility of your data, the power of your analytical work, and the ways both can inform a winning legal strategy.

Access our insights at ***www.pwc.com/us/forensics*** for more information:


Securities Litigation Study: A rising tide or a rogue wave?


Daubert Challenges to Financial Experts


Global Economic Crime Survey: Adjusting the Lens on Economic Crime


PwC's CEO Survey: 20 years inside the mind of the CEO… What's next?

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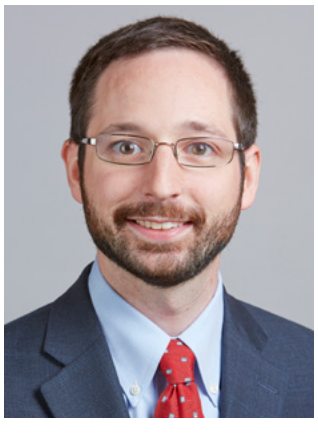

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The Patent Litigation Study team would like to thank Chris Barry for his leadership in making this report a success. We are thankful for your 33 years of dedication to PwC. Best of luck to you on your future endeavors.

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PwC's Forensic Services' team of experienced professionals is dedicated to helping clients meet the challenges related to fraud allegations, financial crimes and other irregularities. Our portfolio of services includes: financial crime examinations, forensic technology solutions, regulatory compliance reviews, fraud risk management and fraud prevention, and dispute analysis and litigation support.

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